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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 740 and 774

[Docket No. 120105019–5755–01]

RIN 0694–AF52

Commerce Control List: Addition of Items Determined To No Longer Warrant Control Under United States Munitions List Category XIV (Toxicological Agents) or Category XVIII (Directed Energy Weapons)

AGENCY: Bureau of Industry and Security, Department of Commerce.

ACTION: Final rule.

SUMMARY: This final rule implements changes described in a proposed rule that the Bureau of Industry and Security (BIS) published on June 17, 2015. Specifically, this final rule describes how articles the President has determined no longer warrant control under Category XIV (Toxicological Agents, Including Chemical Agents, Biological Agents, and Associated Equipment) or Category XVIII (Directed Energy Weapons) of the United States Munitions List (USML) are now controlled under the Commerce Control List (CCL). The affected Category XIV articles consist primarily of dissemination, detection, and protection "equipment" and related articles, such as production and test "equipment," and are controlled under new Export Control Classification Numbers (ECCNs) 1A607, 1B607, 1C607, 1D607, and 1E607, as added to the CCL by this final rule. The affected Category XVIII articles consist primarily of tooling, production "equipment," test and evaluation "equipment," test models, and related articles and are controlled under new ECCNs 6B619, 6D619 and 6E619, as added to the CCL by this final rule.

This final rule is one in a series of rules describing how various types of articles that the President has determined no longer warrant control on the USML, as part of the Administration's Export Control Reform Initiative, are controlled on the CCL in accordance with the requirements of the Export Administration Regulations (EAR).

This final rule is being published by BIS in conjunction with a final rule from the Department of State, Directorate of Defense Trade Controls, which amends the list of articles controlled by USML Categories XIV and XVIII. The citations in this BIS rule to USML Categories XIV and XVIII reflect the amendments contained in the Department of State's rule. The revisions made by BIS in this rule are part of Commerce's retrospective regulatory review plan under Executive Order 13563 completed in August 2011.

DATES: This rule is effective December 31, 2016.

ADDRESSES: The Department of Commerce's full retrospective regulatory review plan can be accessed at: *http://open.commerce.gov/news/2011/08/23/commerce-plan-retrospective-analysis-existing-rules.*

FOR FURTHER INFORMATION CONTACT: For questions regarding dissemination, detection and protection "equipment" and related items that are controlled under new ECCNs 1A607, 1B607, 1C607, 1D607, and 1E607, contact Richard P. Duncan, Ph.D., Director, Chemical and Biological Controls Division, Office of Nonproliferation and Treaty Compliance, Bureau of Industry and Security, telephone: (202) 482–3343, email: *Richard.Duncan@bis.doc.gov.*

For questions regarding tooling, production "equipment," test and evaluation "equipment," test models, and related items that are controlled under new ECCNs 6B619, 6D619 and 6E619, contact Mark Jaso, Sensors and Aviation Division, Office of National Security & Technology Transfer Controls, Bureau of Industry and Security, telephone: (202) 482–0987, email: *Mark.Jaso@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

This final rule is published by the Bureau of Industry and Security (BIS) as part of the Administration's Export Control Reform (ECR) Initiative, the object of which is to protect and enhance U.S. national security interests. The implementation of the ECR initiative includes amendment of the International Traffic in Arms Regulations (ITAR) and its U.S. Munitions List (USML), so that they control only those items that provide the United States with a critical military or intelligence advantage or otherwise warrant such controls, and amendment of the Export Administration Regulations (EAR) to control military items that do not warrant USML controls. This series of amendments to the ITAR and the EAR will reform the U.S. export control system to enhance our national security by: (i) Improving the interoperability of U.S. military forces with allied countries; (ii) strengthening the U.S. industrial base by, among other things, reducing incentives for foreign manufacturers to design out and avoid U.S.-origin content and services; and (iii) allowing export control officials to focus government resources on transactions that pose greater national security, foreign policy, or proliferation concerns than those involving our NATO allies and other multi-regime partners.

Following the structure set forth in the final rule titled "Revisions to the Export Administration Regulations: Initial Implementation of Export Control Reform" (78 FR 22660, April 16, 2013) (hereinafter the "April 16 (initial implementation) rule"), this final rule describes BIS's implementation of controls, under the EAR's CCL, on certain dissemination, detection and protection "equipment" and related articles previously controlled under USML Category XIV in the ITAR and certain tooling, production "equipment," test and evaluation "equipment," test models and related articles previously controlled under USML Category XVIII of the ITAR.

In the April 16 (initial implementation) rule, BIS created a series of new ECCNs to control items that would be removed from the USML and similar items from the Wassenaar Arrangement on Export Controls for Conventional Arms and Dual Use Goods and Technologies Munitions List (Wassenaar Arrangement Munitions List or WAML) that were already controlled elsewhere on the CCL. That final rule referred to this series of new ECCNs as the "600 series," because the third character in each of these new ECCNs is the number "6." The first two characters of the "600 series" ECCNs serve the same function as any other ECCN as described in § 738.2 of the EAR. The first character is a number, within the range of 0 through 9, that identifies the Category on the CCL in which the ECCN is located. The second character is a letter, within the range of A through E, that identifies the product group in a CCL Category. As indicated above, the third character in the "600 series" ECCNs is the number "6," which distinguishes the items controlled under this series of ECCNs from items identified under other ECCNs on the CCL. With few exceptions, the final two characters identify the WAML category that covers items that are the same or similar to items in a particular "600 series" ECCN.

Pursuant to section 38(f) of the Arms Export Control Act (AECA), the President is obligated to review the USML "to determine what items, if any, no longer warrant export controls under" the AECA. The President must report the results of the review to Congress and wait 30 days before removing any such items from the USML. The report must "describe the nature of any controls to be imposed on that item under any other provision of law." 22 U.S.C. 2778(f)(1).

The changes made by this final rule and in the State Department's companion rule to Categories XIV and XVIII of the USML are based on a review of these USML Categories by the Defense Department, which worked with the Departments of State and Commerce in preparing these amendments. Other agencies with expertise and equities in the items at issue in these rules were consulted as well. The review focused on identifying those types of articles that provide the United States with a critical military or intelligence capability and that are not currently in normal commercial use. Such items remain on the USML. Other items with less than a critical military or intelligence capability not in normal commercial use will transition to the "600 series" controls. It is the intent of the agencies that USML Categories XIV and XVIII, and the corresponding "600 series" ECCNs on the CCL, not control items in normal commercial use. Such items should be controlled under existing dual-use controls on the CCL, consistent with the Wassenaar Arrangement List of Dual-Use Goods and Technologies.

All references to the USML in this rule are to the list of defense articles that are controlled for purposes of export, temporary import, or brokering pursuant to the ITAR, and not to the list of defense articles on the United States Munitions Import List (USMIL) that are controlled by the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) for purposes of permanent import under its regulations at 27 CFR part 447. Pursuant to section 38(a)(1) of the AECA, all defense articles controlled for export or import, or that are subject to brokering controls, are part of the "USML" under the AECA. For the sake of clarity, references to the USMIL are to the list of defense articles controlled by ATF for purposes of permanent import. All defense articles described in the USMIL or the USML are subject to the brokering controls administered by the U.S. Department of State in part 129 of the ITAR. The transfer of defense articles from the ITAR's USML to the EAR's CCL, for purposes of export controls, does not affect the list of defense articles that are controlled on the USMIL under the AECA for purposes of permanent import.

On January 18, 2011, the President issued Executive Order 13563, affirming general principles of regulation and directing government agencies to conduct retrospective reviews of existing regulations. The revisions made by this rule are part of Commerce's retrospective regulatory review plan under Executive Order 13563. Commerce's full plan, completed in August 2011, can be accessed at: *http://open.commerce.gov/news/2011/08/23/commerce-plan-retrospective-analysis-existing-rules.*

This final rule implements amendments to the EAR proposed in BIS's rule titled "Commerce Control List: Addition of Items Determined to No Longer Warrant Control under United States Munitions List Category XIV (Toxicological Agents) or Category XVIII (Directed Energy Weapons)," which was published in the **Federal Register** on June 17, 2015 (RIN 0694–AF52) (80 FR 34562) (herein "the June 17 (toxicological agents and directed energy weapons) rule").

Dissemination, Detection and Protection "Equipment" and Related Items

Public Comments and BIS Responses

BIS received comments from eight parties in response to the proposed amendments in the June 17 (toxicological agents and directed energy weapons) rule that addressed dissemination, detection and protection "equipment" and related items.

ECCN 1A607 (Military Dissemination, Detection, and Protection "Equipment")

Comment: One commenter noted that tear gas and riot control agents were dropped from proposed USML Category XIV(d), but did not appear in proposed ECCN 1A607.

Response: The tear gas and riot control agents removed from USML Category XIV(d) are now controlled under ECCN 1C607.a.1 through a.6, as they were proposed to be controlled in BIS's June 17 (toxicological agents and directed energy weapons) rule. Therefore, no further action is required.

ECCN 1A607.f (Protection "Equipment")

Comment: One commenter noted that proposed ECCN 1A607.f included protection "equipment," but did not specifically indicate that it controlled Chemical Agent Resistant Coatings (CARC). The commenter recommended that CARC be specifically identified in ECCN 1A607.f or that the word "material" be added so that companies would be more likely to interpret ECCN 1A607.f to include coatings, such as CARC. In addition, the commenter recommended that the export controls on CARC be changed to align more closely with export controls maintained by U.S. allies, who do not require an export license for CARC to most destinations. Specifically, the commenter felt that companies familiar with the European Union military list could become confused, because the controls in ECCN 1A607.f are similar to those described in ML.7.f, which does not control CARC. In the event that CARC continues to require a license to most destinations, the commenter recommended that all CARC be placed under the export licensing jurisdiction of a single U.S. Government agency to simplify jurisdictional and/or classification determinations.

Response: ECCN 1A607.f indicates that it controls protection "equipment" not controlled by USML Category XIV(f) that is "specially designed" for military use and for defense against materials specified by USML XIV(a) or (b) or riot control agents controlled by ECCN 1C607.a. BIS believes that this control language, as revised in this final rule to specify "protective coatings" (as well as air conditioning units and protective clothing), is now sufficiently clear as to leave no doubt that it applies to paintings/coatings such as CARC. Consequently, the control language used in the June 17 (toxicological agents and directed energy weapons) rule has been retained in this final rule with only the above-referenced change (*i.e.,* the revision of the parenthetical phrase in the introductory text of ECCN 1A607.f to read, as follows: "including air conditioning units, protective coatings, and protective clothing."

As for the scope of the license requirements that apply to CARC, all items in ECCN 1A607, including CARC, are subject to NS Column 1 and RS Column 1 license requirements, which apply to all destinations, except Canada. While the scope of the EAR license requirements on CARC is considerably broader than that maintained by some of our allies, exports of CARC are authorized without a license, under License Exception STA, for destinations in, or nationals of, Country Group A:5 in Supplement No. 1 to part 740 of the EAR, which currently contains 36 countries. Furthermore, the EAR requirements that apply to the CARC that were previously controlled under USML Category XIV and are now controlled under new ECCN 1A607.f represent a significant easing of the regulatory burden on exporters of such CARC through: (i) Elimination of some license requirements; (ii) greater availability of license exceptions; (iii) simpler license application procedures; and (iv) reduced or eliminated registration fees. With respect to the commenter's recommendation that all CARC be placed under the export licensing jurisdiction of a single U.S. Government agency, BIS notes that the only CARC that continue to be controlled under USML Category XIV (specifically, in paragraph (f)(7) of USML Category XIV) are those that have been qualified to one of the following four military specifications: MIL–PRF–32348, MIL–DTL–64159, MIL–C–46168, or MIL–DTL–53039. In light of the anticipated benefits of moving certain CARC from USML Category XIV to new ECCN 1A607 on the EAR's CCL, as described above, there would appear to be little practical upside to continuing to control all CARC under the export licensing jurisdiction of a single U.S. Government agency.

Comment: One commenter recommended that all items identified in USML Category XIV(f)(4) for individual protection against chemical and biological agents specified in USML Category XIV(a) or (b) should be controlled under new ECCN 1A607.f on the CCL. In addition, the commenter recommended that all individual protection "equipment" and clothing controlled under new ECCN 1A607.f should be authorized for export under License Exception BAG under special provisions similar to those currently applicable to "personal protective equipment" (*i.e.*, ECCN 1A613.c or .d) in accordance with Section 740.14(h) of the EAR.

Response: USML Category XIV(f)(4), as set forth in the State Department's companion rule to this final rule, controls equipment or items that offer individual or collective protection against items specified in USML Category XIV(a) or (b), as follows: (1) M53 Chemical Biological Protective Mask or M50 Joint Service General Purpose Mask (JSGPM); (2) filter cartridges containing sorbents controlled in USML Category XIV(f)(4)(iii); (3) ASZM–TEDA carbon; and (4) ensembles, garments, suits, jackets, pants, boots or socks for individual protection, and liners for collective protection, that allow no more than 1% breakthrough of GD, or no more than 2% breakthrough of any other chemical specified in USML Category XIV(a), when evaluated by executing the applicable method(s) of testing described in the current version of Test Operations Procedure (TOP) 08–2–201 (Collective Protection Novel Closures Testing) or 08–2–501 (Permeation Testing of Materials with Chemical Agents or Simulants—Swatch Testing) and using the defined DoD-specific requirements described therein.

The control criteria in USML Category XIV(f)(4), as described above, are the result of a review of USML Category XIV, as part of the Administration's Export Control Reform (ECR) Initiative, to ensure that it controls only those items that are inherently military, provide the United States with a critical military or intelligence advantage, or otherwise warrant control on the USML. In the absence of any compelling evidence contrary to the results of this review, no change is contemplated, with respect to these USML Category XIV criteria, at this time. New ECCN 1A607.f controls "equipment" previously controlled under USML Category XIV(f)(4) or (f)(5) that the President has determined no longer warrants control on the USML (*i.e.*, protection "equipment," including "equipment" for individual protection, not controlled by USML Category XIV(f) that is "specially designed" for military use and for defense against materials specified by USML XIV(a) or (b) or riot control agents controlled by ECCN 1C607.a). This final rule does not expand the scope of new ECCN 1A607.f to control all "equipment" for individual protection against chemical and biological agents specified in USML Category XIV(a) or (b), because this change would be contrary to the President's determination, based on the results of the aforementioned review of USML Category XIV (*i.e.*, it would result in the transfer to the CCL of items that are inherently military, provide the United States with a critical military or intelligence advantage, or otherwise warrant control on the USML).

With respect to the commenter's recommendation that all individual protection "equipment" and clothing controlled under new ECCN 1A607.f should be authorized for export under License Exception BAG (under special provisions similar to those currently applicable to "personal protective equipment"), this final rule amends the License Exception BAG provisions in Section 740.14(h) of the EAR to authorize exports, reexports, or in-country transfers of chemical or biological agent protective gear consistent with the requirements and restrictions described therein. In a corresponding change, this final rule also amends the License Exception TMP provisions in Section 740.9(a)(11) of the EAR to authorize temporary exports, reexports, or in-country transfers of chemical or biological agent protective gear consistent with the requirements and restrictions described therein. These changes are also intended to make the scope of these license exceptions, as they apply to chemical or biological agent protective gear controlled under new ECCN 1A607.f, conform with the scope of the ITAR exemption for personal protective equipment in Section 123.17 of the ITAR.

Comment: One commenter noted that neither BIS's June 17 (toxicological agents and directed energy weapons) rule nor State's companion proposed rule clearly indicated whether filter cartridges containing sorbents funded by the Department of Defense via contract or other funding authorization, as proposed to be controlled under USML Category XIV(n), would be controlled under new ECCN 1A607.f on the CCL or under USML Category XIV(f) or (n). In addition, the commenter noted that neither of these proposed rules clearly indicated whether filter cartridges that meet the requirements of specifications PRF–EA–2251 for the M61 filter cartridge, but do not contain ASZM–TEDA carbon, would be controlled under new ECCN 1A605.f or under USML Category XIV(f) or (n).

Response: Neither of the observations made by the commenter requires any modification to new ECCN 1A607.f. Filter cartridges containing developmental sorbents are controlled under USML Category XIV(f)(4)(ii) if the sorbents were funded by the Department of Defense via contract or other funding authorization, as specified in USML Category XIV(n), and none of the elements in Note 1 to paragraph (n) apply (*i.e.,* the sorbents are determined to be subject to the EAR via a commodity jurisdiction determination or they are identified in the relevant Department of Defense contract or other funding authorization as being developed for both civil and military applications). The commenter's question concerning the export licensing jurisdiction status of filter cartridges reflects the fact that State's companion Category XIV/XVIII proposed rule did not specifically enumerate (in Category XIV) filter cartridges containing sorbents controlled under USML Category XIV(n). USML Category XIV(f)(ii), in State's proposed rule, specified that it controlled filter cartridges containing sorbents controlled under USML Category XIV(f)(iii), but the control status of filter cartridges containing sorbents enumerated in proposed USML Category XIV(n) was not specifically indicated. Consequently, State's companion Category XIV/XVIII final rule corrects this oversight by clarifying USML Category XIV to indicate that it applies to filter cartridges that contain any of the sorbents specified under USML Category XIV(f)(iii) or (n) and, in so doing, eliminates the possibility that such filter cartridges could be controlled under new ECCN 1A607.f on the CCL (except to the limited extent that sorbents funded by the Department of Defense via contract or other funding authorization are excluded from USML Category XIV(n) for a specified period of time, as indicated in Note 3 thereto).

In response to the commenter's request for clarification concerning controls on filter cartridges that meet the requirements of specifications PRF–EA–2251 for the M61 filter cartridge, but do not contain ASZM–TEDA carbon, their control status also would depend upon the sorbents that they contain. As indicated above, filter cartridges that contain any of the sorbents controlled by USML Category XIV (*i.e.,* sorbents specified under paragraph (f)(iii) or (n) of Category XIV) are controlled under USML Category XIV. Otherwise, they are controlled under new ECCN 1A607.f.

ECCN 1A607.h (Detection/Identification "Equipment")

Comment: One commenter interpreted BIS's June 17 (toxicological agents and directed energy weapons) rule and State's companion USML Category XIV/XVIII proposed rule as transferring to new ECCN 1A607.h on the CCL all detection equipment, previously controlled under USML Category XIV(f)(2), that is "specially designed" for military use for the detection of agents identified in proposed USML Category XIV(a) or (b), except for: (1) Detection equipment that is classified or that relates to classified information; and (2) military detection equipment developed under a DoD contract or other funding authorization, as described in proposed USML Category XIV(f)(2) and subject to the restriction in Note 3 thereto, which indicated that the controls in paragraph (f)(2) would apply only to controls dated one year (or later) after the date of publication of State's USML Category XIV final rule. Note 3 to paragraph (f)(2) was mistakenly included in USML Category XIV, as described in State's proposed rule; consequently, it does not appear in State's final rule.

Response: New ECCN 1A607.h controls "equipment" not controlled by USML Category XIV(f) that is "specially designed" for military use and for the detection or identification of materials specified by USML Category XIV(a) or (b) or riot control agents controlled by ECCN 1C607.a on the CCL. Because new ECCN 1A607.h indicates that it does not include any detection equipment that is controlled by USML Category XIV(f), the scope of the ECCN is necessarily dependent upon the scope of Category XIV(f), which, in turn, is subject to interpretation by the U.S. Department of State. Therefore, the Department of State, and not BIS, is the appropriate U.S. Government agency to confirm whether the commenter's statement is correct (in whole or in part), as it applies to the scope of new ECCN 1A607.h and the "equipment" previously controlled under USML Category XIV(f)(2). Consequently, this question should be addressed, with respect to specific detection "equipment," through the submission of one or more commodity jurisdiction (CJ) requests to the State Department's Directorate of Defense Trade Controls (DDTC), consistent with the requirements in the ITAR.

ECCN 1A607.k (Medical Countermeasures)

Comment: One commenter noted that items controlled under proposed new ECCN 1A607.k (military medical countermeasures "equipment"), and related "technology" controlled under proposed new ECCN 1E607.a, would not be eligible for export/reexport under the License Exception GOV provisions in Section 740.11(d), International Inspections under the Chemical Weapons Convention (CWC), to destinations located outside of Country Group A:5 in Supplement No. 1 to part 740 of the EAR.

Response: The commenter is correct in noting that "equipment" in new ECCN 1A607.k and related "technology" in new ECCN 1E607.a are not eligible for export under the License Exception GOV provisions in Section 740.11(d) of the EAR, except to destinations located in Country Group A:5. This restriction, which is described in Section 740.11(d)(2)(iii) of the EAR, was implemented as part of BIS's April 16 (initial implementation) rule in which the License Exception GOV provisions in Section 740.11 of the EAR were revised. Among the License Exception GOV provisions that were affected by these revisions were those authorizing exports and reexports to the Organization for the Prohibition of Chemical Weapons (OPCW) and exports and reexports by the OPCW for official international inspection and verification use under the terms of the CWC. Under the OPCW authorization, as revised, Section 740.11(d)(2)(iii) of the EAR prohibits exports and reexports of items controlled under "600 series" ECCNs on the CCL to countries not listed in Country Group A:5. Country Group A:5 currently consists of 36 countries, as established by BIS's April 16 (initial implementation) rule, which became effective on October 15, 2013. The scope of the OPCW authorization in License Exception GOV was the result of extensive U.S. Government interagency review and discussion. Furthermore, the scope of eligible countries for the OPCW authorization (*i.e.,* 36 countries), as established by BIS's April 16 (initial implementation) rule, was initially broader than the country scope that was authorized under the License Exception GOV provisions for cooperating governments, as described in Section 740.11(c) of the EAR, which then authorized exports and reexports to 27 cooperating governments and agencies of the North Atlantic Treaty Organization (NATO). The country scope of the cooperating governments authorization under License Exception GOV was subsequently expanded, by BIS's Wassenaar Arrangement (WA) 2014 Plenary final rule (98 FR 29432, May 21, 2015), to include 41 cooperating governments and agencies of NATO. Currently, the country scope of the cooperating governments and OPCW authorizations under License Exception GOV are roughly equivalent (*i.e.,* the former applies to four more countries than the latter—two of those countries are CWC States Parties and one is a special administrative region of a State Party). In light of the recent changes to the License Exception GOV provisions described above, BIS does not have any immediate plans to address possible revisions to the country scope of the OPCW authorization. BIS also considers any such action to be outside the scope of this rulemaking, which does not specifically address EAR requirements involving the CWC and the OPCW.

ECCN 1A607.x ("Parts," "Components," "Accessories," and "Attachments")

Comment: One commenter noted that proposed new ECCN 1A607.x indicated that it controlled "parts," "components," "accessories," and "attachments" "specially designed" for the "equipment" described in proposed ECCN 1A607.e, .f, .g, or .j. However, the commenter also noted that "parts," "components," "accessories," and "attachments" "specially designed" for the detection/identification "equipment" described in proposed ECCN 1A607.h were not included in proposed ECCN 1A607.x. As a result, the commenter questioned whether any "parts," "components," "accessories," and "attachments" "specially designed" for detection/identification "equipment" that might be removed from the USML, as a result of the proposed revisions to USML Category XIV(f), would be controlled under proposed new ECCN 1A607 on the CCL (*e.g.*, under proposed ECCN 1A607.x).

Response: The commenter is correct in noting that proposed new ECCN 1A607.x specified only those "parts," "components," "accessories," and "attachments" "specially designed" for the "equipment" described in ECCN 1A607.e, .f, .g, or .j, and not those "parts," "components," "accessories," and "attachments" "specially designed" for detection/identification "equipment" described in ECCN 1A607.h. This final rule corrects that oversight. New ECCN 1A607.x, as added to the CCL by this final rule, indicates that it controls "parts," "components," "accessories," and "attachments" that are "specially designed" for a commodity controlled by ECCN 1A607.e, .f, .g, .h, or .j or for a defense article controlled by USML Category XIV(f) and that are not enumerated or otherwise described elsewhere in the USML.

General Comments on Dissemination, Detection and Protection "Equipment"

Comment: One commenter noted that the BIS and State Category XIV/XVIII proposed rules omitted coverage of the Wassenaar Munitions List (WAML) items in WAML 7.a (Biological agents or radioactive materials adapted for use in war to produce casualties in humans and animals, degrade equipment, or damage crops or the environment).

Response: The items noted by the commenter are not identified in any of the new "600 series" ECCNs described in BIS's June 17 (toxicological agents and directed energy weapons) rule, but they are clearly enumerated under USML Category XIV in State's companion proposed rule. Proposed USML Category XIV(b)(1)(ii) identifies specific biological agents that have been militarized, as described in USML Category XIV(b)(1)(i), and proposed USML Category XIV(b)(2) describes biological agents identified under ECCN 1C351, 1C353, or 1C354 on the EAR's CCL that have been militarized, as described in USML Category XIV(b)(2)(i) and (b)(2)(ii). These defense articles are identified in the USML Category XIV amendments contained in State's companion rule to this final rule.

Comment: One commenter noted that the following two Australia Group (AG) controlled items were not identified in either the BIS or State Category XIV/XVIII proposed rules:

(1) Valves with a closure element designed to be interchangeable, as listed under 6.b on the AG Control List of Dual-Use Chemical Manufacturing Facilities and Equipment); and (2) nose-only exposure apparatus, as listed under 8.b on the AG Control List of Dual-Use Biological Equipment.

Response: The commenter accurately noted that neither of the two items were identified in the BIS and State Category XIV/XVIII proposed rules. However, because these items are identified as dual-use items on the AG common control lists indicated above, neither item is within the scope of this rulemaking. The valves, described under 6.b on the AG chemical manufacturing facilities and equipment control list, are currently controlled under ECCN 2B350.g.2 on the CCL. The nose-only exposure apparatus, described under 8.b on the AG biological equipment common control list, was recently added to this AG control list and is currently controlled under ECCN 2B352.h based on a recent update of AG listed items on the CCL (see 81 FR 36458, June 7, 2016).

Comment: One commenter indicated that some of the proposed new "600 series" ECCNs in BIS's June 17 (toxicological agents and directed energy weapons) rule maintained unilateral controls on certain items that were proposed to be transferred to the CCL from USML Category XIV.

Response: All the items described in the new "600 series" ECCNs created by this final rule were previously controlled on the USML under the ITAR and were added to these new ECCNs on the CCL only after the President determined that these items no longer warrant control on the USML for the reasons set forth above.

Changes Made by This Rule to Controls on Certain Dissemination, Detection and Protection "Equipment" and Related Items Previously Controlled Under USML Category XIV

This final rule creates five new "600 series" ECCNs in CCL Category 1 (ECCNs 1A607, 1B607, 1C607, 1D607, and 1E607) that clarify the EAR controls applicable to certain dissemination, detection and protection "equipment" and related items that the President has determined no longer warrant control under USML Category XIV. Terms such as "part," "component" "accessories," "attachments," and "specially designed" are applied in the same manner in this rule as those terms are defined in Section 772.1 of the EAR. In addition, to assist exporters in determining the control status of their items, a "Specially Designed" Decision Tool and a CCL Order of Review Decision Tool are available on the BIS Web site at: *http://www.bis.doc.gov/index.php/decision-tree-tools.*

New ECCN 1A607 Military dissemination "equipment" for riot control agents, military detection and protection "equipment" for toxicological agents (including chemical, biological, and riot control agents), and related commodities.

In new ECCN 1A607, paragraphs .a through .d, paragraph .i, and paragraphs .l through .w are reserved. Paragraph .e of ECCN 1A607 controls "equipment" "specially designed" for military use and for the dissemination of any of the riot control agents controlled in ECCN 1C607.a. Paragraph .f of ECCN 1A607 controls protection "equipment" "specially designed" for military use and for defense against either materials controlled by USML Category XIV(a) or (b) or any of the riot control agents in new ECCN 1C607.a. Paragraph .g of ECCN 1A607 controls decontamination "equipment" not controlled by USML Category XIV(f) that is "specially designed" for military use and for the decontamination of objects contaminated with materials controlled by USML Category XIV(a) or (b). Paragraph .h controls "equipment" not controlled by USML Category XIV(f) that is "specially designed" for military use and for the detection or identification of either materials specified by USML Category XIV(a) or (b) or riot control agents controlled by new ECCN 1C607.a. Paragraph .j controls "equipment" "specially designed'' to: (i) Interface with a detector, shelter, vehicle, vessel, or aircraft controlled by the USML or a ''600 series'' ECCN; and (ii) collect and process samples of articles controlled in USML Category XIV(a) or (b). Paragraph .k controls medical countermeasures that are ''specially designed'' for military use (including pre- and post-treatments, antidotes, and medical diagnostics) and ''specially designed'' to counter chemical agents controlled by USML Category XIV(a). Paragraph .x controls ''parts,'' ''components,'' ''accessories,'' and ''attachments'' that are ''specially designed'' for a commodity controlled under ECCN 1A607.e, .f, .g, .h, or .j or a defense article controlled in USML Category XIV(f) and that are not enumerated or otherwise described elsewhere in the USML.

New ECCN 1B607 Military test, inspection, and production ''equipment'' and related commodities ''specially designed'' for the ''development,'' ''production,'' repair, overhaul, or refurbishing of commodities identified in ECCN 1A607 or 1C607, or defense articles enumerated or otherwise described in USML Category XIV.

In new ECCN 1B607, paragraph .a controls ''equipment,'' not including incinerators, that is ''specially designed'' for the destruction of chemical agents controlled by USML Category XIV(a). Paragraph .b of ECCN 1B607 controls test facilities and ''equipment'' that are ''specially designed'' for military certification, qualification, or testing of commodities controlled by new ECCN 1A607.e, .f, .g, .h, or .j or by USML Category XIV(f), except for XIV(f)(1). Paragraph .c of ECCN 1B607 controls tooling and ''equipment'' ''specially designed'' for the ''development,'' ''production,'' repair, overhaul, or refurbishing of commodities controlled under new ECCN 1A607.e, .f, .g, .h, or .j or USML Category XIV(f). Paragraphs .d through .w are reserved. Paragraph .x controls ''parts,'' ''components,'' ''accessories,'' and ''attachments,'' not enumerated or otherwise described elsewhere in the USML, that are ''specially designed'' for a commodity controlled by ECCN 1B607.b or .c or for a defense article controlled by USML Category XIV(f).

As indicated above, ECCN 1B607.b does not control test facilities and ''equipment'' that are ''specially designed'' for military certification, qualification, or testing of commodities and are enumerated or otherwise described in USML Category XIV(f)(1), as set forth in State's companion rule to this final rule (*e.g.*, see the equipment in USML Category XIV(f)(1)(ii) that is ''specially designed'' for testing the articles controlled in paragraph (a), (b), (c), (e), or (f)(4) of USML Category XIV). In addition to the test facilities and ''equipment'' controlled by ECCN 1B607.b, see the tooling and ''equipment'' classified under ECCN 2B350 or 2B352 for producing the chemical/biological agents, precursors, or defoliants described in USML Category XIV(a), (b), (c), or (e). The EAR also control tooling and ''equipment'' to produce the antibodies/polynucleotides and vaccines described in USML Category XIV(g) and (h), respectively, as follows: lab ''equipment'' designated as EAR99 under the EAR; biological dual-use ''equipment'' (including protective ''equipment'') classified under ECCN 2B352; and EAR-controlled biological systems for making vaccines (involving the use of mice, rabbits, etc.).

New ECCN 1C607 Tear gases, riot control agents and materials for the detection and decontamination of chemical warfare agents.

New ECCN 1C607.a controls specified tear gases and riot control agents. Paragraph .b of ECCN 1C607 controls ''biopolymers'' not controlled by USML Category XIV(g) that are ''specially designed'' or processed for the detection or identification of chemical warfare (CW) agents specified by USML Category XIV(a) and the cultures of specific cells used to produce them. Paragraph .c controls specified ''biocatalysts'' and biological systems that are not controlled by USML Category XIV(g) and are ''specially designed'' for the decontamination or degradation of CW agents specified by USML Category XIV(a). Paragraph .d controls chemical mixtures not controlled by USML Category XIV(f) that are ''specially designed'' for military use for the decontamination of objects contaminated with materials specified by USML Category XIV(a) or (b).

New ECCN 1D607 ''Software'' ''specially designed'' for the ''development,'' ''production,'' operation, or maintenance of items controlled by 1A607, 1B607 or 1C607.

New ECCN 1D607.a controls ''software'' ''specially designed'' for the ''development,'' ''production,'' operation, or maintenance of items controlled by ECCN 1A607, 1B607 or 1C607. Paragraph .b of ECCN 1D607 is reserved.

New ECCN 1E607 ''Technology'' ''required'' for the ''development,'' ''production,'' operation, installation, maintenance, repair, overhaul, or refurbishing of items controlled by ECCN 1A607, 1B607, 1C607, or 1D607.

New ECCN 1E607.a controls ''technology'' ''required'' for the ''development,'' ''production,'' operation, installation, maintenance, repair, overhaul, or refurbishing of items controlled by ECCN 1A607, 1B607, 1C607, or 1D607. Paragraph .b of ECCN 1E607 is reserved.

Amendments to License Exceptions BAG and TMP related to Individual Protection ''Equipment'' in ECCN 1A607.f.

In response to public comments recommending that all individual protection ''equipment'' and clothing controlled under new ECCN 1A607.f should be authorized for export under License Exception BAG (under special provisions similar to those currently applicable to ''personal protective equipment''), this final rule amends the License Exception BAG provisions in Section 740.14(h) of the EAR to authorize exports, reexports, or in-country transfers of chemical or biological agent protective gear consistent with the requirements and restrictions described therein. In a corresponding change, this final rule also amends the License Exception TMP provisions in Section 740.9(a)(11) of the EAR to authorize temporary exports, reexports, or in-country transfers of chemical or biological agent protective gear consistent with the requirements and restrictions described therein. The amendments to License Exceptions BAG and TMP also change the requirements for Afghanistan to be consistent with those of the majority of other Country Group D:5 destinations (*i.e.*, the U.S. person authorized to use the license exception must be affiliated with the U.S. Government and be traveling on official business or traveling in support of a U.S. Government contract). The same requirement applies to the use of these license exception provisions for Iraq, also a D:5 country, with the additional option that the U.S. person must be traveling to Iraq under a direct authorization by the Government of Iraq and engaging in activities for, on behalf of, or at the request of, the Government of Iraq. These amendments are also intended to ensure that the scope of these license exceptions, as they apply to chemical or biological agent protective gear controlled under new ECCN 1A607.f, conforms with the scope of the ITAR exemption for personal protective equipment in Section 123.17 of the ITAR (*e.g.*, by correcting the provisions for Afghanistan, as described above, to be consistent with those of the majority of other Country Group D:5 destinations).

Tooling, Production "Equipment," Test and Evaluation "Equipment," Test Models and Other Articles Related to Directed Energy Weapons

Public Comments and BIS Responses

BIS received comments from two parties in response to the proposed amendments in the June 17 (toxicological agents and directed energy weapons) rule related to tooling, production "equipment," test, and evaluation "equipment," test models and other articles related to directed energy weapons.

General Comments on Items Related to Directed Energy Weapons

Comment: One commenter noted that the BIS and State Category XIV/XVIII proposed rules omitted coverage of the Wassenaar Munitions List (WAML) items in WAML 19.f ("Laser" systems "specially designed" to cause permanent blindness to unenhanced vision).

Response: The items noted by the commenter are not identified in any of the new "600 series" ECCNs described in BIS's June 17 (toxicological agents and directed energy weapons) rule, but they are clearly enumerated under USML Category XVIII in State's companion proposed rule. Proposed USML Category XVIII(a) identifies directed energy weapons (DEW) systems or "equipment" that, as their sole or primary purpose, cause permanent or flash blindness. These articles are identified in the USML Category XVIII amendments contained in State's companion rule to this final rule.

Comment: One commenter indicated that some of the proposed new "600 series" ECCNs in BIS's June 17 (toxicological agents and directed energy weapons) rule maintained unilateral controls on certain items that were proposed to be transferred to the CCL from the USML Category XVIII.

Response: All the items described in the new "600 series" ECCNs created by this final rule were previously controlled on the USML under the ITAR and were added to these new ECCNs on the CCL only after the President determined that these items no longer warrant control on the USML for the reasons set forth above.

Changes Made by This Rule to Controls on Certain Tooling, Production "Equipment," Test and Evaluation "Equipment" and Test Models Previously Controlled Under USML Category XVIII

This rule creates three new "600 series" ECCNs in CCL Category 6 (ECCNs 6B619, 6D619 and 6E619) that clarify the EAR controls applicable to certain tooling, production "equipment," test and evaluation "equipment," test models, and related articles for Directed Energy Weapons (DEWs) that the President has determined no longer warrant control under USML Category XVIII. Terms such as "part," "component" "accessories," "attachments," and "specially designed" are applied in the same manner in this rule as those terms are defined in Section 772.1 of the EAR. In addition, to assist exporters in determining the control status of their items, a "Specially Designed" Decision Tool and a CCL Order of Review Decision Tool are available on the BIS Web site at: *http://www.bis.doc.gov/index.php/decision-tree-tools.*

New ECCN 6B619 Test, inspection and production "equipment," and related commodities, "specially designed" for the "development," "production," repair, overhaul, or refurbishing of commodities enumerated or otherwise described in USML Category XVIII.

New ECCN 6B619.a controls tooling, templates, jigs, mandrels, molds, dies, fixtures, alignment mechanisms, and test "equipment" not enumerated or otherwise described in USML Category XVIII and not elsewhere specified on the USML that are "specially designed" for the "development," "production," repair, overhaul, or refurbishing of commodities controlled by USML Category XVIII. The commodities that are controlled under new ECCN 6B619.a are used to produce directed energy weapons (including non-lethal directed energy weapons, such as active denial systems) and are similar to commodities that are in operation in a number of other countries, some of which are not allies of the United States or members of multinational export control regimes. Research and development is currently underway to determine the possible uses of such commodities (*e.g.,* to protect the Earth from asteroids, or for perimeter security and crowd control). Possession of such commodities does not confer a significant military advantage on the United States and, therefore, the inclusion of such commodities on the CCL would be appropriate.

Paragraphs .b through .w of ECCN 6B619 are reserved. Paragraph .x controls "parts," "components," "accessories," and "attachments" "specially designed" for a commodity subject to control under paragraph .a of this ECCN and not enumerated or otherwise described in USML Category XVIII and not elsewhere specified on the USML.

New ECCN 6D619 "Software" "specially designed" for the "development," "production," operation or maintenance of commodities controlled by 6B619.

New ECCN 6D619 controls "software" "specially designed" for the "development," "production," operation or maintenance of commodities controlled by ECCN 6B619. Inclusion of this "software" on the CCL is appropriate, because it is limited to "software" "specially designed" for ECCN 6B619 commodities and does not include any "software" for items specifically enumerated or otherwise described on the USML.

New ECCN 6E619 "Technology" "required" for the "development," "production," operation, installation, maintenance, repair, overhaul or refurbishing of commodities controlled by 6B619 or "software" controlled by 6D619.

New ECCN 6E619 controls "technology" "required" for the "development," "production," operation, installation, maintenance, repair, overhaul or refurbishing of commodities controlled by ECCN 6B619, or "software" controlled by 6D619. Inclusion of this "technology" on the CCL is appropriate, because it is limited to "technology" "required" for ECCN 6B619 commodities and does not include any "technology" for items specifically enumerated or otherwise described on the USML.

Applicable Controls for the New "600 Series" ECCNs Created by This Rule

Pursuant to the framework established in the April 16 (initial implementation) rule, detection and protection "equipment" and related commodities classified under ECCN 1A607; related test, inspection and production "equipment" classified under ECCN 1B607; tear gases, riot control agents and related commodities classified under ECCN 1C607 (except for items listed in ECCN 1C607.a.10, .a.11, .a.12, or a.14, all of which are specifically excluded from WAML Category 7 by Note 1 thereto); related "software" classified under ECCN 1D607 (except "software" for items listed in ECCN 1C607.a.10, .a.11, .a.12, or a.14); and related "technology" classified under ECCN 1E607 (except "technology" for items listed in ECCN 1C607.a.10, .a.11, .a.12, or a.14 and 1D607 "software" therefor) are subject to the licensing policies that apply to items controlled for national security (NS) reasons, as described in § 742.4(b)(1)—specifically, NS Column 1 controls. The same level of NS controls and licensing policies also apply to the directed energy weapons items that are controlled under the three new ECCNs (*i.e.,* test, inspection, and production "equipment" classified under ECCN 6B619; related "software" classified under ECCN 6D619; and related "technology" classified under ECCN 6E619) that this rule adds to Category 6 of the CCL. In addition, all the items that are controlled under the new ECCNs created by this rule are subject to the regional stability (RS) licensing policies set forth in § 742.6(a)(1), *i.e.*, RS Column 1, as well as antiterrorism (AT Column 1) and United Nations (UN) controls.

Also, in accordance with §§ 742.4(b)(1) and 742.6(b)(1) of the EAR, exports and reexports of "600 series" items controlled for NS or RS reasons will be reviewed consistent with United States arms embargo policies in § 126.1 of the ITAR, if destined to a country listed in Country Group D:5 of Supplement No. 1 to part 740 of the EAR. All items controlled for NS or RS reasons, as set forth in this final rule, are subject to this licensing policy.

Effects of This Final Rule

BIS believes that the principal effect of this final rule, when considered in the context of similar rules being published as part of the ECR, will be to provide greater flexibility for exports and reexports to NATO member countries and other multiple-regime-member countries of items the President determines no longer warrant control on the USML. This greater flexibility is in the form of: the application of the EAR's *de minimis* threshold principle for items constituting less than a *de minimis* amount of controlled U.S.-origin content in foreign made items; the availability of license exceptions, particularly License Exceptions "Servicing and Replacement of Parts and Equipment" (RPL) and "Strategic Trade Authorization" (STA); the elimination of requirements for manufacturing license agreements and technical assistance agreements in connection with exports of technology; and a reduction in, or the elimination of, exporter and manufacturer registration requirements and associated registration fees. Some of these specific effects are discussed in more detail, below.

De Minimis

The April 16 (initial implementation) rule imposed certain unique *de minimis* requirements on items controlled under the new "600 series" ECCNs. Section 734.3 of the EAR provides, *inter alia*, that, under certain conditions, items made outside the United States that incorporate items subject to the EAR are not subject to the EAR if they do not exceed a "*de minimis*" percentage of controlled U.S. origin content. Under Section 734.4 of the EAR, as amended by the April 16 (initial implementation) rule, there is no eligibility for *de minimis* treatment for a foreign-made item that incorporates U.S.-origin "600 series" items when the foreign-made item is destined for a country that is subject to a U.S. arms embargo, *i.e.*, a country listed in Country Group D:5 of Supplement No. 1 to part 740 of the EAR. Items controlled under the new "600 series" ECCNs created by this rule are eligible for *de minimis* treatment under the EAR, provided that the foreign-made items into which they are incorporated are not destined for a country listed in Country Group D:5. In contrast, the AECA does not permit the ITAR to have a *de minimis* treatment for USML-listed items, regardless of the significance or insignificance of the U.S.-origin content or the percentage of U.S.-origin content in the foreign-made item (*i.e.*, USML-listed items remain subject to the ITAR when they are incorporated abroad into a foreign-made item, regardless of either of these factors).

Use of License Exceptions

The April 16 (initial implementation) rule imposed certain restrictions on the use of license exceptions for items controlled under "600 series" ECCNs on the CCL. The general restrictions that apply to the use of license exceptions for such items are described in § 740.2(a)(13) of the EAR. The EAR provisions that describe the requirements specific to individual license exceptions contain additional restrictions on the use of license exceptions for such items.

For example, this rule authorizes limited License Exception STA availability for the new "600 series" ECCNs contained herein. None of the items controlled under these new ECCNs are eligible for the STA "controls of lesser sensitivity" described in § 740.20(c)(2) of the EAR. Instead, STA eligibility for all such items is limited to the destinations listed in § 740.20(c)(1) of the EAR (*i.e.*, Country Group A:5 destinations indicated in Supplement No. 1 to part 740 of the EAR). In addition, such items must be for: (1) ultimate end-use by a person of a type specified in § 740.20(b)(3)(ii) of the EAR (*i.e.*, the armed forces, police, paramilitary, law enforcement, customs, correctional, fire, or a search and rescue agency of a government of one of the countries listed in Country Group A:5 or the United States Government); or (2) the "development," "production," operation installation, maintenance, repair, overhaul, or refurbishing of an item, in one of the countries listed in Country Group A:5 or the United States, that will ultimately be used by any such government agencies, the United States Government, or by a person in the United States. The use of License Exception STA also may be authorized, under certain circumstances described in § 740.20(b)(3)(ii)(C), where the U.S. Government has otherwise authorized the ultimate end-use under a license.

None of the items controlled under the new "600 series" ECCNs created by this rule are treated as "end items" for purposes of License Exception STA and, therefore, such items are not subject to the License Exception STA eligibility request requirements in § 740.20(g) of the EAR.

Items controlled under new ECCN 1B607 or 6B619 are also eligible for License Exception LVS (limited value shipments) up to a value of $1,500, TMP (temporary exports), and RPL (servicing and replacement parts). License Exceptions TMP and RPL also are available for items controlled under new ECCN 1A607. In addition, special provisions in License Exception TMP (see § 740.9(a)(11) of the EAR) and License Exception BAG (baggage) (see § 740.14(h) of the EAR), as amended by this final rule, authorize exports, reexports, or in-country transfers of certain protection "equipment" described in ECCN 1A607.f.

BIS believes that the restrictions that apply to the use of license exceptions for the items in the new "600 series" ECCNs represents an overall reduction from the level of restrictions that previously applied to such items on the USML. This is particularly true with respect to exports of such items to NATO members and multiple-regime member countries.

Alignment With the Wassenaar Arrangement Munitions List

Since the beginning of ECR, the Administration has stated that the reforms will be consistent with the United States' obligations to the multilateral export control regimes. Accordingly, the Administration has, in this final rule, exercised its national discretion to implement, clarify, and, to the extent feasible, align its controls with those of the regimes. In this rule, new ECCNs 1A607 and 1C607 implement, to the extent possible, the controls in WAML Category 7; new ECCNs 1B607 and 6B619 implement, to the extent possible, the controls in WAML Category 18 for production "equipment;" new ECCNs 1D607 and 6D619 implement, to the extent possible, the controls in WAML

Category 21 for "software;" and new ECCNs 1E607 and 6E619 implement, to the extent possible, the controls in WAML Category 22 for "technology."

Export Administration Act

Although the Export Administration Act expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013), and as extended by the Notice of August 7, 2015 (80 FR 48233 (Aug. 11, 2015), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*). BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222 as amended by Executive Order 13637.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a "significant regulatory action," although not economically significant, under Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget (OMB).

2. Notwithstanding any other provision of law, no person is required to respond to, nor is any person subject to a penalty for failure to comply with, a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid OMB control number. This final rule affects the following approved collections: Simplified Network Application Processing System (control number 0694–0088), which includes, among other things, license applications; License Exceptions and Exclusions (0694–0137); recordkeeping (0694–0096); export clearance (0694–0122); and the Automated Export System (0607–0152). The discussion, below, is intended to provide a general overview of possible burden changes as a result of all the ECR rules published by BIS, and not just this final rule, which affects items previously controlled under USML Category XIV or XVIII. No changes in burden for any of these collections is anticipated at this time, other than as indicated in the discussion, below.

As stated in the proposed rule published on July 15, 2011 (76 FR 41958) (the "July 15 proposed rule"), BIS initially estimated that the combined effect of all rules to be published, adding items to the EAR that would be removed from the ITAR as part of the Administration's Export Control Reform Initiative, would increase the number of license applications to be submitted to BIS by approximately 16,000 annually, resulting in an increase in burden hours of 5,067 (16,000 transactions at 17 minutes each) under control number 0694–0088. As the review of the USML has progressed, the interagency group has gained more specific information about the number of items that would come under BIS jurisdiction and whether those items would be eligible for export under license exception. As of June 21, 2012, BIS revised its estimate to reflect an increase in license applications of 30,000 annually, resulting in an increase in burden hours of 8,500 (30,000 transactions at 17 minutes each) under control number 0694–0088. BIS continues to believe that its revised estimate is accurate. Notwithstanding this increase in license applications under the EAR, the net burden that U.S. export controls impose on U.S. exporters is expected to go down, as described below, as a result of the transfer of less sensitive military items to the jurisdiction of the Department of Commerce, under the EAR, and the application of the license exceptions and other provisions in the EAR that are described in this final rule.

As implemented by this rule, certain dissemination, detection and protection "equipment" and related articles currently controlled under USML Category XIV in the ITAR and certain tooling, production "equipment," test and evaluation "equipment," test models and related articles currently controlled under USML Category XVIII of the ITAR are now subject to the licensing jurisdiction of the Department of Commerce under the EAR and its CCL, and also are eligible for certain license exceptions, including License Exception STA. For example, items controlled under new ECCN 1A607, 1B607, 1C607, 1D607, 1E607, 6B619, 6D619, or 6E619 are now eligible under certain provisions of License Exception STA and do not need a determination of eligibility as described in § 740.20(g) of the EAR. BIS believes that the increased use of License Exception STA resulting from the combined effect of all rules to be published, adding items to the EAR that would be removed from the ITAR as part of the Administration's Export Control Reform Initiative, would increase the burden associated with control number 0694–0137 by about 23,858 hours (20,450 transactions at 1 hour and 10 minutes each).

BIS expects that this increase in burden hours under the EAR will be more than offset by a reduction in the burden hours associated with currently approved collections related to the ITAR. With few exceptions, most exports of the dissemination, detection and protection "equipment" and related articles and the tooling, production "equipment," test and evaluation "equipment," test models and related articles that this rule adds to the CCL previously required State Department authorization, even when destined to NATO member states and other close allies. In addition, the exports of "technology" necessary to produce such items in the inventories of the United States and its NATO and other close allies previously required State Department authorization. Under the EAR, as implemented by this rule, such "technology" is now eligible for export to NATO member states and other close allies under License Exception STA, unless otherwise specifically excluded.

The anticipated reduction in burden hours will particularly impact exporters of "parts" and "components" that are no longer be subject to the ITAR, because, with few exceptions, the ITAR exempt from license requirements only exports to Canada. Most exports of such "parts" and "components," even when destined to NATO and other close allies, previously required State Department authorization. Under the EAR, as implemented by this rule, a small number of low-level "parts" and "components" do not require a license to most destinations, while most other "parts" and "components" identified under the new "600 series" ECCNs are eligible for export to NATO and other close allies under License Exception STA.

Use of License Exception STA imposes a paperwork and compliance burden because, for example, exporters must furnish information about the item that is being exported to the consignee and obtain from the consignee an acknowledgement and commitment to comply with the requirements of the EAR. However, the Administration believes that complying with the requirements of STA is likely to be less burdensome than applying for licenses. For example, under License Exception STA, a single consignee statement can apply to an unlimited number of products, need not have an expiration date and need not be submitted to the government in advance for approval. Suppliers with regular customers can tailor a single statement and assurance to match their business relationship, rather than applying repeatedly for licenses with every purchase order, to supply allied and, in some cases, U.S. forces with routine replacement parts and components.

Even in situations in which a license is required under the EAR, the burden likely will be reduced, compared to the previous license requirement under the ITAR. In particular, license applications for exports of "technology" controlled by ECCN 1E607 or 6E619 are likely to be less complex and burdensome than the authorizations required to export ITAR-controlled "technology," *i.e.*, Manufacturing License Agreements and Technical Assistance Agreements.

3. This rule does not contain policies with Federalism implications as that term is defined under E.O. 13132.

4. The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 *et seq.*, generally requires an agency to prepare an initial regulatory flexibility analysis (IRFA) for any rule subject to the notice and comment rulemaking requirements under the Administrative Procedure Act (5 U.S.C. 553) or any other statute, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Under section 605(b) of the RFA, however, if the head of an agency certifies that a rule will not have a significant impact on a substantial number of small entities, the RFA does not require the agency to prepare a regulatory flexibility analysis. Accordingly, pursuant to section 605(b), the Chief Counsel for Regulation, Department of Commerce, has certified to the Chief Counsel for Advocacy, Small Business Administration, that this proposed rule, if promulgated, will not have a significant impact on a substantial number of small entities. The rationale for this certification is as follows.

Number of Small Entities

Although BIS does not collect data on the size of entities that apply for, and are issued, export licenses and is, therefore, unable to estimate the exact number of small entities—as defined by the Small Business Administration's regulations implementing the RFA—BIS acknowledges that some small entities may be affected by this proposed rule.

Economic Impact

The amendments set forth in this rule are part of the Administration's ECR initiative, which seeks to revise the USML to be a positive control list—one that does not use generic, catch-all control text to describe items subject to the ITAR—and to move some items that the President has determined no longer warrant control under the ITAR to control under the EAR and its CCL. Such items, along with certain military items currently identified on the CCL (most of which are identified on the WAML), will be controlled under new "600 series" ECCNs on the CCL. In addition, certain other items currently on the CCL will move from existing ECCNs to the new "600 series" ECCNs.

This rule addresses certain dissemination, detection and protection "equipment" and related articles previously enumerated or otherwise described in USML Category XIV (Toxicological Agents, Including Chemical Agents, Biological Agents, and Associated Equipment) and certain tooling, production "equipment," test and evaluation "equipment," test models and related articles previously enumerated or otherwise described in USML Category XVIII (Directed Energy Weapons). Most toxicological agents (*i.e.*, chemical and biological agents) and associated equipment and all Directed Energy Weapons (DEWs) systems "specially designed" or modified for military applications, equipment "specially designed" or modified to detect, identify or defend against such systems, and "specially designed" "parts," "components," "accessories" and "attachments" for such systems or equipment remain on the USML. However, many other "parts" and "components" are now subject to the EAR (as items described in ECCN 1A607.x, 1B607.x, or 6B619.x), unless specifically enumerated or otherwise described on the USML. Many of these "parts" and "components" are more likely, than the USML articles described above, to be produced by small businesses. In addition, officials of the Department of State have informed BIS that license applications for such "parts" and "components" represent a high percentage of the license applications for USML articles reviewed by that department. Changing the jurisdictional status of certain Category XIV and Category XVIII items will reduce the burden on small entities (and other entities as well) through: (i) Elimination of some license requirements; (ii) greater availability of license exceptions; (iii) simpler license application procedures; and (iv) reduced or eliminated registration fees.

Moreover, "parts" and "components" that are controlled under the ITAR remain under ITAR control when incorporated into foreign-made items, regardless of the significance or insignificance of the item. This discourages foreign buyers from incorporating such U.S. content. The availability of *de minimis* treatment under the EAR, for those items that are no longer controlled under the ITAR, may reduce the disincentive for foreign manufacturers to purchase U.S.-origin "parts" and "components," a development that potentially would mean greater sales for U.S. suppliers, including small entities.

Many exports and reexports of the Category XIV or Category XVIII articles that are added to the CCL by this rule (particularly, the "parts" and "components" that are controlled under new ECCN 1A607.x, 1B607.x, or 6B619.x) are now eligible for license exceptions that apply to exports to U.S. Government agencies, exports of "parts" and "components" for use as replacement parts, temporary exports and limited value exports (for ECCN 1B607 and 6B619 items, only), as well as License Exception STA, thereby reducing the number of licenses that exporters will need to obtain for these items. License exceptions under the EAR allow suppliers to send routine replacement parts and low level parts to NATO and other close allies and export control regime partners for use by those governments and for use by contractors building equipment for those governments or for the U.S. Government without having to obtain export licenses. Under License Exception STA, the exporter needs to furnish information about the item being exported to the consignee and obtain a statement from the consignee that, among other things, will commit the consignee to comply with the EAR and other applicable U.S. laws. Because such statements and obligations can apply to an unlimited number of transactions and have no expiration date, they will result in a net reduction in burden on transactions routinely approved by the government through the license application process that the License Exception STA statements would replace.

Even for exports and reexports for which a license will be required, the process for obtaining a license is simpler and less costly under the EAR. When a USML Category XIV or Category

XVIII article is moved to the CCL, the number of destinations for which a license is required remains unchanged. However, the burden on the license applicant decreases because the licensing procedure for CCL items is simpler and more flexible than the licensing procedure for USML articles.

Under the USML licensing procedure, an applicant must include a purchase order or contract with its application. There is no such requirement under the CCL licensing procedure. This difference gives the CCL applicant at least two advantages. First, the applicant has a way to determine whether the U.S. Government will authorize the transaction before it enters into potentially lengthy, complex and expensive sales presentations or contract negotiations. Under the USML procedure, the applicant must caveat all sales presentations with a reference to the need for government approval, and is more likely to engage in substantial effort and expense only to find that the government will reject the application. Second, a CCL license applicant need not limit its application to the quantity or value of one purchase order or contract. It may apply for a license to cover all of its expected exports or reexports to a specified consignee over the life of a license (normally four years, but maybe longer if circumstances warrant a longer period), thus reducing the total number of licenses for which the applicant must apply.

In addition, many applicants exporting or reexporting items that this rule transfers from the USML to the CCL will realize cost savings through the elimination of some or all registration fees assessed under the USML's licensing procedure. Currently, USML applicants must pay to use the USML licensing procedure even if they never actually are authorized to export. Registration fees for manufacturers and exporters of articles on the USML start at $2,250 per year, increase to $2,750 for organizations applying for one to ten licenses per year and further increase to $2,750 plus $250 per license application (subject to a maximum of three percent of total application value) for those who need to apply for more than ten licenses per year. Conversely, there are no registration or application processing fees for applications to export items listed on the CCL. Entities who applied for licenses from the Department of State, for the Category XIV or Category XVIII items subject to this rulemaking that are removed from the USML and added to the CCL, will find their registration fees reduced if the number of USML licenses those entities need declines. If an entity's entire product line moves to the CCL, its ITAR registration and registration fee requirement will be eliminated.

Conclusion

BIS expects that the changes to the EAR implemented by this rule will have a positive effect on all affected entities, including small entities. While BIS acknowledges that this rule may have some cost impacts on small (and other) entities, those costs are more than offset by the benefits to the entities from the licensing procedures under the EAR, which are much less costly and less time consuming than the procedures under the ITAR. As noted above, any new burdens created by this rule will be offset by a reduction in the number of items that will require a license, increased opportunities for use of license exceptions for exports to certain countries, simpler export license applications, reduced or eliminated registration fees and application of a *de minimis* threshold for foreign-made items incorporating U.S.-origin parts and components, all of which will reduce the incentive for foreign buyers to design out or avoid U.S.-origin content. Accordingly, the Chief Counsel for Regulation, Department of Commerce, has certified to the Chief Counsel for Advocacy, Small Business Administration, that this rule, if implemented, would not have a significant economic impact on a substantial number of small entities. Accordingly, an initial regulatory flexibility analysis is not required, and none has been prepared.

List of Subjects

15 CFR Part 740

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

15 CFR Part 774

Exports, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, parts 740 and 774 of the Export Administration Regulations (15 CFR parts 730–774) are amended as follows:

PART 740—[AMENDED]

■ 1. The authority citation for 15 CFR part 740 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 7201 *et seq.;* E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 7, 2015, 80 FR 48233 (August 11, 2015).

■ 2. Section 740.9 is amended by revising paragraph (a)(11) to read as follows:

§ 740.9 Temporary imports, exports, reexports, and transfers (in-country) (TMP).

* * * * *

(a) * * *

(11) *Personal protective "equipment" classified under ECCN 1A613.c or .d and individual protection "equipment" classified under ECCN 1A607.f*—(i) *Temporary exports, reexports, or in-country transfers to countries not identified in Country Group D:5.* U.S. persons may temporarily export or reexport one set of body armor classified under ECCN 1A613.d (which may include one helmet classified under ECCN 1A613.c) or one set of chemical or biological agent protective gear classified under ECCN 1A607.f (which may include one additional filter canister classified under ECCN 1A607.x) to countries not identified in Country Group D:5, provided that:

(A) The items are with the U.S. person's baggage or effects, whether accompanied or unaccompanied (but not mailed); *and*

(B) The items are for that U.S. person's exclusive use and not for transfer of ownership unless reexported or transferred (in-country) to another U.S. person.

(ii) *Temporary exports, reexports, or transfers (in-country) to countries identified in Country Group D:5*—(A) *Iraq.* U.S. persons may temporarily export or reexport one set of body armor classified under ECCN 1A613.d (which may include one helmet classified under ECCN 1A613.c) or one set of chemical or biological agent protective gear classified under ECCN 1A607.f (which may include one additional filter canister classified under ECCN 1A607.x) to Iraq, for personal use, provided that the requirements in paragraph (a)(11)(i) of this section are met. In addition, the U.S. person must be affiliated with the U.S. Government and traveling on official business or traveling in support of a U.S. Government contract, or the U.S. person must be traveling to Iraq under a direct authorization by the Government of Iraq and engaging in activities for, on behalf of, or at the request of, the Government of Iraq. Documentation regarding direct authorization from the Government of Iraq shall include an English translation.

(B) *Other countries in Country Group D:5.* U.S. persons may temporarily export or reexport one set of body armor classified under ECCN 1A613.d (which may include one helmet classified under ECCN 1A613.c) or one set of chemical or biological agent protective gear classified under ECCN 1A607.f (which may include one additional filter canister classified under ECCN 1A607.x) to countries in Country Group D:5 (except Iraq), for personal use, provided that the requirements in paragraph (a)(11)(i) of this section are met, and the U.S. person is affiliated with the U.S. Government traveling on official business or is traveling in support of a U.S. Government contract.

(iii) Items exported, reexported, or transferred (in-country) under this paragraph (a)(11), if not consumed or destroyed in the normal course of authorized temporary use abroad, must be returned to the United States or other country from which the items were so transferred as soon as practicable but no later than four years after the date of export, reexport or transfer (in-country).

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■ 3. Section 740.14 is amended by revising paragraphs (h)(1) and (2) to read as follows:

§ 740.14 Baggage (BAG).

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(h) *Special provisions: personal protective "equipment" classified under ECCN 1A613.c or .d and individual protection "equipment" classified under ECCN 1A607.f*—(1) *Exports, reexports, or in-country transfers to countries not identified in Country Group D:5.* U.S. persons may export, reexport, or transfer (in-country) one set of body armor classified under ECCN 1A613.d (which may include one helmet classified under ECCN 1A613.c) or one set of chemical or biological agent protective gear classified under ECCN 1A607.f (which may include one additional filter canister classified under ECCN 1A607.x) to countries not identified in Country Group D:5, provided that:

(i) The items are with the U.S. person's baggage or effects, whether accompanied or unaccompanied (but not mailed); *and*

(ii) The items are for that person's exclusive use and not for transfer of ownership unless reexported or transferred (in-country) to another U.S. person.

(2) *Exports, reexports, or in-country transfers to countries identified in Country Group D:5*—(i) *Iraq.* U.S. persons may export, reexport, or transfer (in-country) one set of body armor classified under ECCN 1A613.d (which may include one helmet classified under ECCN 1A613.c) or one set of chemical or biological agent protective gear classified under ECCN 1A607.f (which may include one additional filter canister classified under ECCN 1A607.x) to Iraq, for personal use, provided that the requirements in paragraph (h)(1) of this section are met. In addition, the U.S. person must be affiliated with the U.S. Government and traveling on official business or traveling in support of a U.S. Government contract, or the U.S. person must be traveling to Iraq under a direct authorization by the Government of Iraq and engaging in activities for, on behalf of, or at the request of, the Government of Iraq. Documentation regarding direct authorization from the Government of Iraq shall include an English translation.

(ii) *Other countries in Country Group D:5.* U.S. persons may export, reexport, or transfer (in-country) one set of body armor classified under ECCN 1A613.d (which may include one helmet classified under ECCN 1A613.c) or one set of chemical or biological agent protective gear classified under ECCN 1A607.f (which may include one additional filter canister classified under ECCN 1A607.x) to countries in Country Group D:5 (except Iraq), for personal use, provided that the requirements in paragraph (h)(1) of this section are met, and the U.S. person is affiliated with the U.S. Government traveling on official business or is traveling in support of a U.S. Government contract.

* * * * *

PART 774—[AMENDED]

■ 4. The authority citation for part 774 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.;* 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. app. 5; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 7, 2015, 80 FR 48233 (August 11, 2015).

■ 5. In Supplement No. 1 to part 774 (the Commerce Control List), Category 1—Special Materials and Related Equipment, Chemicals, "Microorganisms," and "Toxins," add ECCN 1A607 between ECCNs 1A290 and 1A613 to read as follows:

Supplement No. 1 to Part 774—the Commerce Control List

* * * * *

1A607 Military dissemination "equipment" for riot control agents, military detection and protection "equipment" for toxicological agents (including chemical, biological, and riot control agents), and related commodities (see List of Items Controlled).

License Requirements

Reason for Control: NS, RS, AT, UN

Control(s)	*Country chart (see Supp. No. 1 to Part 738)*
NS applies to entire entry.	NS Column 1
RS applies to entire entry.	RS Column 1
AT applies to entire entry.	AT Column 1
UN applies to entire entry.	See § 746.1(b) for UN controls

List Based License Exceptions (See Part 740 for a description of all license exceptions)

LVS: N/A

GBS: N/A

CIV: N/A

Special Conditions for STA

STA: Paragraph (c)(2) of License Exception STA (§ 740.20(c)(2) of the EAR) may not be used for any item in 1A607.

List of Items Controlled

Related Controls: (1) Vaccines identified in ECCN 1C991 are not controlled by this ECCN. (2) See 22 CFR 121.1 (USML), Category XIV(h), for vaccines that are subject to the ITAR. (3) Protection and detection equipment and related items identified in ECCN 1A004, 1A995, or 2B351 are not controlled by this ECCN. (4) See 22 CFR 121.1 (USML), Category XIV(f), for dissemination, detection and protection equipment that is subject to the ITAR. (5) See ECCN 0A919 for "military commodities" located and produced outside the United States that incorporate more than a *de minimis* amount of US-origin "600 series" controlled content.

Related Definitions: N/A

Items:

a. through d. [Reserved]

e. "Equipment" "specially designed" for military use and for the dissemination of any of the riot control agents controlled in ECCN 1C607.a.

f. Protection "equipment" (including air conditioning units, protective coatings, and protective clothing):

f.1. Not controlled by USML Category XIV(f); *and*

f.2. "Specially designed" for military use and for defense against:

f.2.1. Materials specified by USML Category XIV (a) or (b); *or*

f.2.2. Riot control agents controlled in 1C607.a.

g. Decontamination "equipment":

g.1. Not controlled by USML Category XIV(f); *and*

g.2. "Specially designed" for military use and for decontamination of objects contaminated with materials controlled by USML Category XIV(a) or (b).

h. "Equipment":

h.1. Not controlled by USML Category XIV(f); *and*

h.2. "Specially designed" for military use and for the detection or identification of:

h.2.1. Materials specified by USML Category XIV(a) or (b); *or*

h.2.2. Riot control agents controlled by ECCN 1C607.a.

i. [Reserved]

j. "Equipment" "specially designed" to:

j.1. Interface with a detector, shelter, vehicle, vessel, or aircraft controlled by the USML or a "600 series" ECCN; *and*

j.2. Collect and process samples of articles controlled in USML Category XIV(a) or (b).

k. Medical countermeasures that are "specially designed" for military use (including pre- and post-treatments, antidotes, and medical diagnostics) and "specially designed" to counter chemical agents controlled by the USML Category XIV(a).

Note: *Examples of "equipment" controlled by this entry are barrier and non-barrier creams and filled autoinjectors (e.g., combopens where one injector contains 2–PAM and the other atropine) if "specially designed" to counter such agents.*

l. through w. [Reserved]

x. "Parts," "components," "accessories," and "attachments" that are "specially designed" for a commodity controlled by ECCN 1A607.e, .f, .g, .h, or .j or for a defense article controlled by USML Category XIV(f) and that are not enumerated or otherwise described elsewhere in the USML.

■ 6. In Supplement No. 1 to part 774 (the Commerce Control List), Category 1—Special Materials and Related Equipment, Chemicals, "Microorganisms," and "Toxins," add ECCN 1B607 between ECCNs 1B234 and 1B608 to read as follows:

1B607 Military test, inspection, and production "equipment" and related commodities "specially designed" for the "development," "production," repair, overhaul, or refurbishing of commodities identified in ECCN 1A607 or 1C607, or defense articles enumerated or otherwise described in USML Category XIV (see List of Items Controlled).

License Requirements

Reason for Control: NS, RS, AT, UN

Control(s)	*Country chart (see Supp. No. 1 to Part 738)*
NS applies to entire entry.	NS Column 1
RS applies to entire entry.	RS Column 1
AT applies to entire entry.	AT Column 1
UN applies to entire entry.	See § 746.1(b) for UN controls

List Based License Exceptions (See Part 740 for a description of all license exceptions)

LVS: $1500
GBS: N/A
CIV: N/A

Special Conditions for STA

STA: Paragraph (c)(2) of License Exception STA (§ 740.20(c)(2) of the EAR) may not be used for any item in 1B607.

List of Items Controlled

Related Controls: (1) See ECCN 2B350 for controls on certain incinerators. (2) See ECCN 0A919 for "military commodities" located and produced outside the United States that incorporate more than a *de minimis* amount of US-origin "600 series" controlled content.

Related Definitions: N/A

Items:

a. "Equipment" "specially designed" for the destruction of the chemical agents controlled by USML Category XIV(a).

Note to 1B607.a: *ECCN 1B607.a includes controls over facilities "specially designed" for destruction operations. This paragraph .a does not control incinerators and "specially designed" handling facilities or "specially designed" waste supply systems therefor.*

b. Test facilities and "equipment" "specially designed" for military certification, qualification, or testing of commodities controlled by ECCN 1A607.e, .f, .g, .h, or .j or by USML Category XIV(f), except for XIV(f)(1).

c. Tooling and "equipment" "specially designed" for the "development," "production," repair, overhaul, or refurbishing of commodities controlled by ECCN 1A607.e, .f .g, .h, or .j or USML Category XIV(f).

d. through w. [RESERVED]

x. "Parts," "components," "accessories," and "attachments" that are "specially designed" for a commodity controlled by ECCN 1B607.b or .c, or for a defense article controlled by USML Category XIV(f), and that are not enumerated or otherwise described elsewhere in the USML.

■ 7. In Supplement No. 1 to part 774 (the Commerce Control List), Category 1—Special Materials and Related Equipment, Chemicals, "Microorganisms," and "Toxins," add a new ECCN 1C607 between ECCNs 1C395 and 1C608 to read as follows:

1C607 Tear Gases, Riot Control Agents and materials for the detection and decontamination of chemical warfare agents (see List of Items Controlled).

License Requirements

Reason for Control: NS, RS, AT, UN

Control(s)	*Country chart (see Supp. No. 1 to Part 738)*
NS applies to entire entry, except 1C607.a.10, .a.11, .a.12, and .a.14.	NS Column 1
RS applies to entire entry.	RS Column 1
AT applies to entire entry.	AT Column 1
UN applies to entire entry.	See § 746.1(b) for UN controls

List Based License Exceptions (See Part 740 for a description of all license exceptions)

LVS: N/A
GBS: N/A
CIV: N/A

Special Conditions for STA

STA: Paragraph (c)(2) of License Exception STA (§ 740.20(c)(2) of the EAR) may not be used for any item in 1C607.

List of Items Controlled

Related Controls: (1) See ECCN 1A984 for controls on other riot control agents. (2) See 22 CFR 121.1 (USML), Category XIV(b), for modified biological agents and biologically derived substances that are subject to the ITAR. (3) See 22 CFR 121.1 (USML), Category XIV(g), for ITAR controls on antibodies, recombinant protective antigens, polynucleotides, biopolymers or biocatalysts (including the expression vectors, viruses, plasmids, or cultures of specific cells used to produce them) that are "specially designed" for use with articles controlled under USML Category XIV(f). (4) See ECCN 0A919 for "military commodities" located and produced outside the United States that incorporate more than a *de minimis* amount of US-origin "600 series" controlled content.

Related Definitions: N/A

Items:

a. Tear gases and riot control agents including:

a.1. CA (Bromobenzyl cyanide) (CAS 5798–79–8);

a.2. CS (o-Chlorobenzylidenemalononitrile or o-Chlorobenzalmalononitrile) (CAS 2698–41–1);

a.3. CN (Phenylacyl chloride or w-Chloroacetophenone) (CAS 532–27–4);

a.4. CR (Dibenz-(b,f)-1,4-oxazephine) (CAS 257–07–8);

a.5. Adamsite (Diphenylamine chloroarsine or DM) (CAS 578–94–9);

a.6. N-Nonanoylmorpholine, (MPA) (CAS 5299–64–9);

a.7. Dibromodimethyl ether (CAS 4497–29–4);

a.8. Dichlorodimethyl ether (ClCi) (CAS 542–88–1);

a.9. Ethyldibromoarsine (CAS 683–43–2);

a.10. Bromo acetone (CAS 598–31–2);

a.11. Bromo methylethylketone (CAS 816–40–0);

a.12. Iodo acetone (CAS 3019–04–3);

a.13. Phenylcarbylamine chloride (CAS 622–44–6);

a.14. Ethyl iodoacetate (CAS 623–48–3);

Note to 1C607.a: *ECCN 1C607.a. does not control the following: formulations containing 1% or less of CN or CS; individually packaged tear gases or riot control agents for personal self-defense purposes that are controlled by ECCN 1A984; or active constituent chemicals, and combinations thereof, identified and packaged for food production or medical purposes.*

b. "Biopolymers," not controlled by USML Category XIV(g) "specially designed" or processed for the detection or identification of chemical warfare agents specified by USML Category XIV(a), and the cultures of specific cells used to produce them.

c. "Biocatalysts," and biological systems therefor, not controlled by USML Category XIV(g) "specially designed" for the decontamination or degradation of chemical warfare agents controlled in USML Category XIV (a), as follows:

c.1. "Biocatalysts" "specially designed" for the decontamination or degradation of chemical warfare agents controlled in USML Category XIV(a) resulting from directed laboratory selection or genetic manipulation of biological systems;

c.2. Biological systems containing the genetic information specific to the production of "biocatalysts" specified by 1C607.c.1, as follows:

c.2.a. "Expression vectors;"

c.2.b. Viruses; *or*

c.2.c. Cultures of cells.

Note to 1C607.b and .c: *The cultures of cells and biological systems are exclusive and these sub-items do not apply to cells or biological systems for civil purposes, such as agricultural, pharmaceutical, medical, veterinary, environmental, waste management, or in the food industry.*

d. Chemical mixtures not controlled by USML Category XIV(f) "specially designed" for military use for the decontamination of objects contaminated with materials specified by USML Category XIV(a) or (b).

■ 8. In Supplement No. 1 to part 774 (the Commerce Control List), Category 1—Special Materials and Related Equipment, Chemicals, "Microorganisms," and "Toxins," add ECCN 1D607 between ECCNs 1D390 and 1D608 to read as follows:

1D607 "Software" "specially designed" for the "development," "production," operation, or maintenance of items controlled by 1A607, 1B607 or 1C607 (see List of Items Controlled).

License Requirements

Reason for Control: NS, RS, AT, UN

Control(s)	*Country chart (see Supp. No. 1 to Part 738)*
NS applies to entire entry, except "software" for 1C607.a.10, .a.11, .a.12, and .a.14.	NS Column 1
RS applies to entire entry.	RS Column 1
AT applies to entire entry.	AT Column 1
UN applies to entire entry.	See § 746.1(b) for UN controls

List Based License Exceptions (See Part 740 for a description of all license exceptions)

CIV: N/A
TSR: N/A

Special Conditions for STA

STA: Paragraph (c)(2) of License Exception STA (§ 740.20(c)(2) of the EAR) may not be used for any item in 1D607.

List of Items Controlled

Related Controls: (1) "Software" directly related to articles enumerated or otherwise described in USML Category XIV is subject to the ITAR (see 22 CFR § 121.1, Category XIV(m)). "Software" controlled by USML Category XIV(m) includes "software" directly related to any equipment containing reagents, algorithms, coefficients, software, libraries, spectral databases, or alarm set point levels developed under U.S. Department of Defense contract or funding for the detection, identification, warning or monitoring of items controlled in paragraphs (a) or (b) of USML Category XIV, or for chemical or biological agents specified by U.S. Department of Defense funding or contract. (2) See ECCN 0A919 for "military commodities" located and produced outside the United States that incorporate more than a *de minimis* amount of US-origin "600 series" controlled content.

Related Definitions: N/A

Items:

a. "Software" "specially designed" for the "development," "production," operation, or maintenance of commodities controlled by ECCN 1A607, 1B607, or 1C607.

b. [RESERVED]

■ 9. In Supplement No. 1 to part 774 (the Commerce Control List), Category 1—Special Materials and Related Equipment, Chemicals, "Microorganisms," and "Toxins," add a new ECCN 1E607 between ECCNs 1E355 and 1E608 to read as follows:

1E607 "Technology" "required" for the "development," "production," operation, installation, maintenance, repair, overhaul, or refurbishing of items controlled by ECCN 1A607, 1B607, 1C607, or 1D607 (see List of Items Controlled).

License Requirements

Reason for Control: NS, RS, AT, UN

Control(s)	*Country chart (see Supp. No. 1 to Part 738)*
NS applies to entire entry, except "technology" for 1C607.a.10, .a.11, .a.12, and .a.14 and for 1D607 "software" therefor.	NS Column 1
RS applies to entire entry.	RS Column 1
AT applies to entire entry.	AT Column 1
UN applies to entire entry.	See § 746.1(b) for UN controls

List Based License Exceptions (See Part 740 for a description of all license exceptions)

CIV: N/A
TSR: N/A

Special Conditions for STA

STA: Paragraph (c)(2) of License Exception STA (§ 740.20(c)(2) of the EAR) may not be used for any item in 1E607.

List of Items Controlled

Related Controls: Technical data directly related to defense articles enumerated or otherwise described in USML Category XIV are subject to the ITAR (see 22 CFR § 121.1, Category XIV(m)). Technical data controlled by USML Category XIV(m) include technical data directly related to any equipment containing reagents, algorithms, coefficients, software, libraries, spectral databases, or alarm set point levels developed under U.S. Department of Defense contract or funding for the detection, identification, warning or monitoring of items controlled in paragraphs (a) or (b) of USML Category XIV, or for chemical or biological agents specified by U.S. Department of Defense funding or contract.

Related Definitions: N/A

Items:

a. "Technology" "required" for the "development," "production," operation, installation, maintenance, repair, overhaul, or refurbishing of items controlled by ECCN 1A607, 1B607, 1C607 or 1D607.

Note to 1E607.a: ECCN 1E607.a includes "technology" "required" exclusively for the incorporation of "biocatalysts" controlled by ECCN 1C607.c.1 into military carrier substances or military material.

b. [RESERVED]

■ 10. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 6—Sensors and Lasers," add a new ECCN 6B619 between ECCNs 6B108 and 6B995 to read as follows:

6B619 Test, inspection, and production "equipment" and related commodities "specially designed" for the "development," "production," repair, overhaul, or refurbishing of commodities enumerated or otherwise described in USML Category XVIII (see List of Items Controlled)

License Requirements

Reason for Control: NS, RS, AT, UN

Control(s)	*Country chart (see Supp. No. 1 to Part 738)*
NS applies to entire entry.	NS Column 1
RS applies to entire entry.	RS Column 1
AT applies to entire entry.	AT Column 1
UN applies to entire entry.	See § 746.1(b) for UN controls

License Exceptions

LVS: $1500
GBS: N/A
CIV: N/A

Special Conditions for STA

STA: Paragraph (c)(2) of License Exception STA (§ 740.20(c)(2) of the EAR) may not be used for any item in 6B619.

List of Items Controlled

Related Controls: "Parts," "components," "accessories," "attachments," and associated systems or "equipment" "specially designed" for defense articles enumerated or otherwise described in paragraphs (a) or (b) of USML Category XVIII are subject to the ITAR (see 22 CFR 121.1, Category XVIII(e)).

Related Definitions: N/A
Items:

a. Tooling, templates, jigs, mandrels, molds, dies, fixtures, alignment mechanisms, and test "equipment" not enumerated or otherwise described in USML Category XVIII and not elsewhere specified on the USML that are "specially designed" for the "development," "production," repair, overhaul, or refurbishing of commodities controlled by USML Category XVIII.

b. through w. [Reserved]

x. "Parts," "components," "accessories," and "attachments" "specially designed" for a commodity subject to control under paragraph .a of this ECCN and not enumerated or otherwise described in USML Category XVIII and not elsewhere specified on the USML.

■ 11. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 6—Sensors and Lasers," add a new ECCN 6D619 between ECCNs 6D201 and 6D991 to read as follows:

6D619 "Software" "specially designed" for the "development," "production," operation or maintenance of commodities controlled by 6B619.

License Requirements

Reason for Control: NS, RS, AT, UN

Control(s)	*Country chart (see Supp. No. 1 to Part 738)*
NS applies to entire entry.	NS Column 1
RS applies to entire entry.	RS Column 1
AT applies to entire entry.	AT Column 1
UN applies to entire entry.	See § 746.1(b) for UN controls

License Exceptions

CIV: N/A
TSR: N/A

Special Conditions for STA

STA: Paragraph (c)(2) of License Exception STA (§ 740.20(c)(2) of the EAR) may not be used for any item in 6D619.

List of Items Controlled

Related Controls: "Software" directly related to articles enumerated or otherwise described in USML Category XVIII is subject to the ITAR (See 22 CFR 121.1, Category XVIII(f)).
Related Definitions: N/A
Items:

The list of items controlled is contained in the ECCN heading.

■ 12. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 6—Sensors and Lasers," add ECCN 6E619 between ECCNs 6E202 and 6E990 to read as follows:

6E619 "Technology" "required" for the "development," "production," operation, installation, maintenance, repair, overhaul or refurbishing of commodities controlled by 6B619 or "software" controlled by 6D619.

License Requirements

Reason for Control: NS, RS, AT, UN

Control(s)	*Country chart (see Supp. No. 1 to Part 738)*
NS applies to entire entry.	NS Column 1
RS applies to entire entry.	RS Column 1
AT applies to entire entry.	AT Column 1
UN applies to entire entry.	See § 746.1(b) for UN controls

License Exceptions

CIV: N/A
TSR: N/A

Special Conditions for STA

STA: Paragraph (c)(2) of License Exception STA (§ 740.20(c)(2) of the EAR) may not be used for any item in 6E619.

List of Items Controlled

Related Controls: Technical data directly related to articles enumerated or otherwise described in USML Category XVIII are subject to the ITAR (See 22 CFR 121.1, Category XVIII(f)).
Related Definitions: N/A
Items:

The list of items controlled is contained in the ECCN heading.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2016–17506 Filed 7–27–16; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF STATE

22 CFR Part 121

[Public Notice: 9466]

RIN 1400–AD03

Amendment to the International Traffic in Arms Regulations: Revision of U.S. Munitions List Categories XIV and XVIII

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: As part of the President's Export Control Reform effort, the Department of State amends the International Traffic in Arms Regulations (ITAR) to revise Categories XIV (toxicological agents, including chemical agents, biological agents, and associated equipment) and XVIII (directed energy weapons) of the U.S. Munitions List (USML) to describe more precisely the articles warranting control on the USML. The revisions contained in this rule are part of the Department of State's retrospective plan under E.O. 13563, completed on August 17, 2011. The Department of State's full plan can be accessed at *http://www.state.gov/documents/organization/181028.pdf.*

DATES: This Final rule is effective on December 31, 2016.

FOR FURTHER INFORMATION CONTACT: Mr. C. Edward Peartree, Director, Office of Defense Trade Controls Policy, Department of State, telephone (202) 663–2792; email *DDTCPublicComments@state.gov.* ATTN: ITAR Amendment—USML Categories XIV and XVIII.

SUPPLEMENTARY INFORMATION: The Directorate of Defense Trade Controls (DDTC), U.S. Department of State, administers the International Traffic in Arms Regulations (ITAR) (22 CFR parts 120–130). The items subject to the jurisdiction of the ITAR, *i.e.,* "defense articles," are identified on the ITAR's U.S. Munitions List (USML) (22 CFR 121.1). With few exceptions, items not subject to the export control jurisdiction of the ITAR are subject to the jurisdiction of the Export Administration Regulations ("EAR," 15 CFR parts 730–774, which includes the Commerce Control List (CCL) in Supplement No. 1 to Part 774), administered by the Bureau of Industry and Security (BIS), U.S. Department of Commerce. Both the ITAR and the EAR impose license requirements on exports and reexports. Items not subject to the ITAR or to the exclusive licensing jurisdiction of any other set of regulations are subject to the EAR.

All references to the USML in this rule are to the list of defense articles controlled for the purpose of export or temporary import pursuant to the ITAR, and not to the defense articles on the USML that are controlled by the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATFE) for the purpose of permanent import under its regulations. *See* 27 CFR part 447. Pursuant to section 38(a)(1) of the Arms Export Control Act (AECA), all defense articles controlled for export or import are part of the USML under the AECA. The list of defense articles controlled by ATFE for the purpose of permanent import is the U.S. Munitions Import List (USMIL). The transfer of defense articles from the ITAR's USML to the EAR's CCL does not affect the list of defense articles controlled on the USMIL.

Revision of Category XIV

This final rule revises USML Category XIV, covering toxicological agents, including chemical agents, biological agents, and associated equipment. The revisions are undertaken in order to more accurately describe the articles within the subject categories, and to establish a "bright line" between the USML and the CCL for the control of these articles. The Department published a proposed rule for these revisions on June 17, 2015 (80 FR 34572).

This final rule adopts for those pathogens and toxins that meet specific capabilities listed in paragraph (b) the "Tier 1" pathogens and toxins established in the Department of Health and Human Services and the United States Department of Agriculture select agents and toxins regulations (42 CFR part 73 and 9 CFR part 121). The Tier 1 pathogens and toxins that do not meet these capabilities remain controlled in Export Control Classification Number (ECCN) 1C351 on the CCL.

Additionally, this rule, in concert with the analogous rule published by the Department of Commerce, moves riot control agents to the export jurisdiction of the Department of Commerce, as well as the articles covered previously in paragraphs (j), (k), and (l), which include test facilities, equipment for the destruction of chemical and biological agents, and tooling for production of articles in paragraph (f), respectively.

Other changes include the addition of paragraph (a)(5) to control chemical warfare agents "adapted for use in war" and not elsewhere enumerated, as well as the removal of paragraphs (f)(3) and (f)(6) and movement to the CCL of equipment for the sample collection and decontamination or remediation of chemical agents and biological agents. Paragraph (f)(5) for collective protection was removed and partially combined in paragraph (f)(4) or the CCL. Paragraph (g) enumerates antibodies, recombinant protective antigens, polynucleotides, biopolymers, or biocatalysts exclusively funded by a Department of Defense contract for detection of the biological agents listed in paragraph (b)(1)(ii).

The Department notes that the controls in paragraph (f)(2) that include the phrase "developed under a Department of Defense contract or other funding authorization" do not apply when the Department of Defense acts solely as a servicing agency for a contract on behalf of another agency of the U.S. government. Moreover, "other funding authorization" refers to other funding authorization from the Department of Defense.

The Department notes that the controls in paragraphs (g)(1) and (h) that include the phrase "exclusively funded by a Department of Defense contract" do not apply when the Department of Defense acts solely as a servicing agency for a contract on behalf of another agency of the U.S. government, or, for example, in cases where the Department of Defense provides initial funding for the development of an item but another agency of the U.S. government provides funding to further develop or adapt the item.

Paragraph (h) enumerates certain vaccines funded exclusively by the Department of Defense, as well as certain vaccines controlled in (h)(4) that are specially designed for the sole purpose of protecting against biological agents and biologically derived substances identified in (b). Thus, the scope of vaccines controlled in (h)(4) is circumscribed by the nature of funding and the satisfaction of the term "specially designed" as that term is defined in ITAR § 120.41. In evaluating the scope of this control, please note that the Department offers a decision tool to aid exporters in determining whether a defense article meets the definition of "specially designed." This tool is available at *http://www.pmddtc.state.gov/licensing/dt_SpeciallyDesigned.htm.*

Paragraph (i) is updated to provide better clarity on the scope of the control by including examples of Department of Defense tools that are used to determine or estimate potential effects of chemical or biological weapons strikes and incidents in order to plan to mitigate their impacts.

A new paragraph (x) has been added to USML Category XIV, allowing ITAR licensing on behalf of the Department of Commerce for commodities, software, and technology subject to the EAR, provided those commodities, software, and technology are to be used in or with defense articles controlled in USML Category XIV and are described in the purchase documentation submitted with the application. The intent of paragraph (x) is not to impose ITAR jurisdiction on commodities, software, and technology subject to EAR controls. Items described in paragraph (x) remain subject to the jurisdiction of the EAR. The Department added the paragraph as a regulatory reference point in response to industry requests to be able to use a Department of State license to export shipments that have a mix of ITAR controlled items and EAR controlled items for use in or with items described in that category.

Finally, this rule establishes USML control in subparagraph (f)(2) of certain chemical or biological agent equipment only when it contains reagents, algorithms, coefficients, software, libraries, spectral databases, or alarm set point levels developed under a Department of Defense contract or other funding authorization.

One commenter questioned whether the use of the words "to include" in proposed paragraph (a) was meant to indicate an all-inclusive list or only examples of controlled agents. The Department has modified paragraph (a) to replace "to include" with the all-inclusive "as follows" in light of this comment, and in order to align this language with the comparable language that appears in paragraph (b).

A commenting party suggested that the removal of former subparagraph (n)(2) would inhibit university research with respect to agents controlled by paragraph (a). The Department disagreed with this comment because former subparagraph (n)(2) applied only to agents controlled in paragraph (b).

Several commenters expressed confusion with respect to subparagraph (b)(1), arguing that, for example, the list in subparagraph (b)(1)(ii) was incomplete, or represented a migration to ITAR control of agents or research formerly subject to the EAR. The Department clarifies that all of the biological agents subject to control under revised paragraph (b) were also subject to ITAR control under former paragraph (b), which generally controlled those biological agents or biologically derived substances that were specifically developed, configured, adapted, or modified for the purpose of increasing their capability to produce casualties in humans or livestock, degrade equipment, or damage crops.

By contrast, subparagraph (b)(1) of revised Category XIV controls only those agents that meet the criteria of both subparagraphs (b)(1)(i) and (b)(1)(ii). To be controlled, the agent must be one of the specific listed microorganisms or toxins, or their non-naturally occurring genetic elements, *and* it must have been modified in a manner that is known or reasonably expected to result in an increase of at least one of two specific criteria. Subparagraph (b)(2) controls only biological agents that meet the criteria of subparagraph (b)(2)(i) *and* do so in a manner that is known or reasonably expected to result in an increase of at least one of three specific criteria in (b)(2)(ii). Subparagraphs (b)(1) and (b)(2) represent a narrowing of the universe of agents subject to control under the paragraph (b), and a more specific means of control than the broad, generic language of former paragraph (b).

One commenting party recommended an exclusion in paragraph (b) for research funded by the National Institutes of Health, the Centers for Disease Control and Prevention, or the U.S. Department of Agriculture. Given the refined and narrowed scope of control in paragraph (b) as described above, which focuses on specific and weaponized biological agents, the Department disagreed with this suggestion because it is overly broad.

Four commenting parties argued that regulation of biological agents in paragraph (b) is not necessary in the manner proposed because of the existence of the Federal Select Agent Program and the Dual Use Research of Concern policy. The Department disagreed with these comments because the referenced program and policy are not munitions export control regimes and do not share the national security and foreign policy objectives of the ITAR. As stated above, the articles described in revised paragraph (b) were subject to the ITAR under the previous Category XIV and do not include any biological agents that were not previously subject to the ITAR; as such, there is no expansion of control beyond what existed previously, and the relationship between these agents and the Federal Select Agent Program or Dual Use Research of Concern policy is unchanged.

One commenting party observed that subparagraph (b)(1)(ii) of the proposed rule adopted the Tier 1 list of select agents meeting certain criteria, but did not incorporate the exclusions of the Federal Select Agent Program. Revised Category XIV is not intended to intersect with the Federal Select Agent Program. The ITAR and Federal Select Agent Program do not share identical objectives; accordingly, it would be inappropriate to provide common exclusions for largely unrelated regulatory concerns.

Four commenters requested the reinstatement of former subparagraph (n)(2), which provided an exclusion for agents otherwise controlled in paragraph (b) that had been modified for civil applications. The Department disagreed with these comments because, as noted above, paragraph (b) has been reduced in scope significantly to control only weaponized strains of specified agents. By contrast, former paragraph (b) required the subparagraph (n)(2) exclusion because it was otherwise overly broad. Since the revised paragraph (b) does not capture modifications that would be undertaken for civil applications that do not merit control, the subparagraph (n)(2) exclusion is no longer appropriate.

One commenting party stated that former paragraph (b) was in essence an empty box because the export licensing of biological agents as munitions would violate the Biological Weapons Convention (BWC). The Department disagreed with this comment because such treatment of biological agents does not violate the BWC when used in the development of countermeasures, which serve "prophylactic" or "protective" purposes explicitly permitted by the BWC. Moreover, prevention of the acquisition of weaponized biological agents for impermissible purposes, as is achieved through regulation of such agents under the ITAR, is consistent with the objectives of the BWC.

A commenter expressed the view that based on proposed paragraph (b), an expression vector that produces Ebola virus envelope protein for use in pseudotyping minimal lentiviral vectors, even though harmless in itself, might be subject to ITAR control because the envelope is a pathogenicity factor to Ebola virus, even in the absence of Ebola virus. The Department disagrees with this comment because the described item would not be controlled by paragraph (b) unless it satisfied the criteria of subparagraph (b)(1)(i), particularly taken together with Note 2 to paragraph (b).

One commenter suggested that the list of biological agents in paragraph (b)(1)(ii) fails to take into account the danger and exposure risk presented by each toxin. The Department notes, as stated above, that the list in subparagraph (b)(1)(ii) does not stand alone as a list of agents subject to control. To be subject to the ITAR, an agent listed in subparagraph (b)(1)(ii) must also meet the criteria of subparagraph (b)(1)(i).

Four commenting parties indicated that the properties referenced in subparagraph (b)(1)(i) and (b)(2)(ii) are not properties for which researchers would typically test, and that the proposed language might result in mandatory testing for these properties to avoid inadvertent violations. The Department revised the language in these subparagraphs to limit the analysis of modifications to those that are known to or are reasonably expected to result in an increase in the subject properties.

Two commenters suggested that the research subject to control in subparagraph (b)(1) should focus on the intent or purpose of the research. The Department disagreed with this comment in light of the revisions made to subparagraphs (b)(1)(i) and (b)(2)(ii) in response to public comments, and also in order to avoid the introduction of an intent or end use-based control, which has been a longstanding objective of the ECR initiative.

Three commenting parties observed that the use of "*e.g.*" in subparagraph (b)(1)(i)(A) suggests that the parenthetical examples of persistence in a field environment is not complete. The Department changed "*e.g.*" to "*i.e.*," and updated the parenthetical list accordingly.

One commenter requested a definition of "persistence in a field environment" in subparagraph (b)(2)(i)(A) to avoid ambiguity. The Department refined the subparagraph to provide more comprehensive criteria.

Three commenters noted that ECCN 1C352 has been combined with ECCN 1C351, and that any references to the former should be deleted from Category XIV. The Department agrees with these comments.

Two commenting parties submitted comments that suggested a misunderstanding that references in subparagraph (b)(2) to ECCNs 1C351, 1C353, and 1C354 would move agents controlled under those ECCNs to the jurisdiction of the Department of State. No biological agents are moved from the CCL to the USML as a result of this rulemaking, nor was such movement suggested in the proposed rule. The ECCNs are referenced merely in order to better define the articles subject to control, to which the criteria of both subparagraphs (b)(2)(i) and (b)(2)(ii) must apply.

Two commenting parties observed that the use of "*e.g.*" in subparagraph (b)(2)(ii)(A) suggests that the parenthetical examples of persistence in a field environment is not complete. The Department changed "*e.g.*" to "*i.e.*," and updated the parenthetical list accordingly.

Similarly, two commenting parties observed that the use of "*e.g.*" in subparagraph (b)(2)(ii)(B) indicates that the list of possible dispersal characteristics is not complete. In this case, the Department confirms that the parenthetical list is intended to be exemplary in nature.

One commenter stated that Note 2 to paragraph (b)'s limitation to wild type agents is still unnecessarily restrictive with respect to the agents listed in subparagraph (b)(1)(ii). The Department disagreed with this comment because, as indicated previously, to be subject to the ITAR an agent listed in subparagraph (b)(2)(ii) must also meet the criteria of subparagraph (b)(2)(i).

A commenter remarked that the controls described in the proposed rule would establish ITAR control over technical data and research and development activities related to, *inter alia,* biological agents described in paragraph (b). Bearing in mind the fact that all agents controlled under revised paragraph (b) were subject to control under former paragraph (b), the Department believes that control over such information and activities is appropriate given the narrowed scope of revised paragraph (b) to specific weaponized biological agents.

A commenting party identified typographical errors in subparagraphs (c)(4) and (c)(5). The Department made the appropriate corrections.

Two commenters requested clarification regarding the phrase "Department of Defense contract or funding authorization," as it appears in subparagraphs (f)(1)(ii), (f)(2), and (f)(2)(ii). The Department clarifies that the quoted language captures a range of possible Department of Defense funding authorization mechanisms that extend beyond contracts, such as grants. While these subparagraphs do not require exclusive funding by the Department of Defense to cause the articles to become subject to ITAR control, and there is no *de minimis* funding level that triggers control, the use of "specially designed" in certain of these subparagraphs limits the scope of control, in addition to other specific criteria set forth in the subparagraphs.

A commenting party questioned the intent and meaning of Note 3 to paragraph (f)(2). The Department deleted the note.

Two commenting parties recommended a revision to subparagraph (f)(2)(i) to control only relevant equipment for chemical or biological agents specified in the Department of Defense contract or other funding authorization as intended for control under USML Category XIV, or to clarify the funding mechanism that specifies the chemical or biological agent and thus triggers the provision. The Department disagreed with the former comment because it would introduce a discretionary contract mechanism that could allow for the subjective application or removal of ITAR control, but modified the subparagraph to better define the scope of control. The modifications clarify the link between the funding mechanisms referenced in subparagraph (f)(2) and (f)(2)(ii).

One commenting party recommended the movement to the EAR of all articles controlled in subparagraph (f)(4), or the removal of the Significant Military Equipment (SME) designation at a minimum. The Department disagreed with this comment because the commenter did not provide a sufficient rationale to compel removal from the USML or the SME designation for these articles.

A comment recommended that subparagraph (f)(4)(iii) be revised to remove the trade name ASZM–TEDA and instead specify the parameters or criteria that merit control for activated carbon products. The Department revised the subparagraph to reference the specification that merits control.

Two commenters observed that paragraph (f)(4)(iv) would not distinguish between military and non-military protective apparel, but would rely on a "breakthrough test" that could capture garments designed to National Fire Protection Association standards or designed to integrate with civil gas masks if they met breakthrough levels. The Department has refined subparagraph (f)(4)(iv) to the same paragraph to more precisely describe the articles that warrant control and incorporated the elements described in the prior Note into the control parameters.

One commenting party recommended that Chemical Agent Resistant Coatings (CARC) be moved from subparagraph (f)(7) to the EAR. The Department updated the subparagraph to control the appropriate specification, but disagreed with the remainder of the comment in order to maintain ITAR control over coatings that have been qualified to military specifications.

A commenter suggested the replacement of the word "qualified" in subparagraph (f)(7) with the phrase "meet the requirements of." The Department disagreed with this comment because the phrasing used is intended to mean that the article has in fact been qualified by the Department of Defense to the relevant standard.

One commenting party recommended the removal of the SME designation for subparagraph (f)(7). The Department disagreed with this comment because the commenter did not provide a sufficient rationale for removal of the designation.

Three commenting parties suggested that subparagraph (g)(1) should control relevant articles based on parameters or criteria other than the funding source. The Department notes that subparagraph (g)(1) controls only those relevant articles that are exclusively funded by the Department of Defense, for detection of the biological agents listed in subparagraph (b)(1)(ii). The Department believes that this is an appropriately tailored subparagraph, particularly in light of the requirement that Department of Defense funding be exclusive.

One commenter presented a similar comment with respect to the analogous exclusive funding provision in subparagraph (h). Again, the Department disagrees with this comment because the exclusive funding requirement narrows the range of controlled vaccines to an appropriate scope.

A commenting party suggested that the use of specially designed in paragraph (h) undermines the notion of control due to funding source, as certain vaccines could be released through ITAR § 120.41(b). The Department disagrees with this comment because it is not likely that ITAR § 120.41(b) would allow for the release of vaccines that were exclusively funded by the Department of Defense to protect against biological agents controlled under paragraph (b).

A commenter requested clarification as to whether subparagraph (h)(4) is subject to the requirement that the vaccine be funded exclusively by a Department of Defense contract or other funding authorization. Since this exclusive funding requirement appears in subparagraph (h), the Department confirms that this is the case.

Revision of Category XVIII

This final rule revises USML Category XVIII, covering directed energy weapons. As with USML Category XIV, the revisions are undertaken in order to more accurately describe the articles within the subject categories, and to establish a "bright line" between the USML and the CCL for the control of these articles. This final rule revises paragraph (a) to control only those articles that, other than as a result of incidental, accidental, or collateral effect, achieve the effects described in the paragraph by way of non-acoustic techniques.

The articles controlled previously in paragraphs (c) and (d) are moved to the export control jurisdiction of the Department of Commerce.

The remaining paragraphs in this category underwent conforming changes to bring their structures into alignment with the analogous provisions found in other revised USML categories.

A commenting party suggested that the reference in proposed paragraph (a) to the "primary purpose" of system or equipment at issue was unclear. The Department revised the paragraph to remove this language and clarify the intended scope of control.

Two commenting parties recommended revisions to the structure of paragraph (a). The Department revised the paragraph text to enhance clarity and readability.

A commenter noted that "flash blindness," as used in proposed paragraph (a), has no commonly understood meaning. The Department revised the subject language to clarify the intended scope of control.

One commenting party recommended the addition of a note to paragraph (a) to confirm that the paragraph does not control articles subject to control under subparagraphs XI(a)(4)(iii) or XII(b)(9). The Department disagrees with this comment because the USML Order of Review establishes that the paragraph that most specifically identifies a given article will control that article; accordingly, it is not necessary to add clarifying notes of this nature.

A commenter observed that it was not clear what "associated systems or equipment" meant in proposed paragraph (e). The Department revised the paragraph to match the structure of analogous paragraphs found in other revised USML categories.

A commenting party recommended a note to paragraph (e) that would indicate that components, parts, accessories, attachments and associated systems or equipment specially designed for articles controlled under paragraph XVIII(e) are subject to the EAR. Noting that no such note has been applied to the analogous paragraphs in other revised USML categories, the Department disagrees with this comment because the inclusion of "specially designed" in paragraph (e) provides the intended scope of control for the articles at issue.

Regulatory Findings

Administrative Procedure Act

The Department of State is of the opinion that controlling the import and export of defense articles and services is a foreign affairs function of the United States Government and that rules implementing this function are exempt from sections 553 (Rulemaking) and 554 (Adjudications) of the Administrative Procedure Act. Although the Department is of the opinion that this rule is exempt from the rulemaking provisions of the APA, the Department published this rule as a proposed rule (80 FR 34572) with a 60-day provision for public comment and without prejudice to its determination that controlling the import and export of defense services is a foreign affairs function.

Regulatory Flexibility Act

Since the Department is of the opinion that this rule is exempt from the rulemaking provisions of 5 U.S.C. 553, it does not require analysis under the Regulatory Flexibility Act.

Unfunded Mandates Reform Act of 1995

This amendment does not involve a mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This amendment has been found not to be a major rule within the meaning of the Small Business Regulatory Enforcement Fairness Act of 1996.

Executive Orders 12372 and 13132

This amendment will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this amendment does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this amendment.

Executive Order 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributed impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a "significant regulatory action," although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget (OMB).

Executive Order 12988

The Department of State has reviewed the amendment in light of sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13175

The Department of State has determined that this rulemaking will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not preempt tribal law. Accordingly, Executive Order 13175 does not apply to this rulemaking.

Paperwork Reduction Act

Following is a listing of approved collections that will be affected by revision of the U.S. Munitions List (USML) and the Commerce Control List pursuant to the President's Export Control Reform (ECR) initiative. This rule continues the implementation of ECR. The list of collections pertains to revision of the USML in its entirety, not only to the categories published in this rule. The Department is not proposing or making changes to these collections in this rule. The information collections impacted by the ECR initiative are as follows:

(1) Statement of Registration, DS–2032, OMB No. 1405–0002.

(2) Application/License for Permanent Export of Unclassified Defense Articles and Related Unclassified Technical Data, DSP–5, OMB No. 1405–0003.

(3) Application/License for Temporary Import of Unclassified Defense Articles, DSP–61, OMB No. 1405–0013.

(4) Application/License for Temporary Export of Unclassified Defense Articles, DSP–73, OMB No. 1405–0023.

(5) Application for Amendment to License for Export or Import of Classified or Unclassified Defense Articles and Related Technical Data, DSP–6, –62, –74, –119, OMB No. 1405–0092.

(6) Request for Approval of Manufacturing License Agreements, Technical Assistance Agreements, and Other Agreements, DSP–5, OMB No. 1405–0093.

(7) Maintenance of Records by Registrants, OMB No. 1405–0111.

List of Subjects in 22 CFR Part 121

Arms and munitions, Exports.

Accordingly, for the reasons set forth above, title 22, chapter I, subchapter M, part 121 is amended as follows:

PART 121—THE UNITED STATES MUNITIONS LIST

■ 1. The authority citation for part 121 continues to read as follows:

Authority: Secs. 2, 38, and 71, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2797); 22 U.S.C. 2651a; Pub. L. 105–261, 112 Stat. 1920; Section 1261, Pub. L. 112–239; E.O. 13637, 78 FR 16129.

■ 2. Section 121.1 is amended by revising U.S. Munitions List Categories XIV and XVIII to read as follows:

§ 121.1 The United States Munitions List.

* * * * *

Category XIV—Toxicological Agents, Including Chemical Agents, Biological Agents, and Associated Equipment

*(a) Chemical agents, as follows:

(1) Nerve agents, as follows:

(i) O-Alkyl (equal to or less than C_{10}, including cycloalkyl) alkyl (Methyl, Ethyl, n-Propyl or Isopropyl) phosphonofluoridates, such as: Sarin (GB): O-Isopropyl methylphosphonofluoridate (CAS 107–44–8) (CWC Schedule 1A); and Soman (GD): O-Pinacolyl methylphosphonofluoridate (CAS 96–64–0) (CWC Schedule 1A);

(ii) O-Alkyl (equal to or less than C_{10}, including cycloalkyl) N,N-dialkyl (Methyl, Ethyl, n-Propyl or Isopropyl) phosphoramidocyanidates, such as: Tabun (GA): O-Ethyl N, N-dimethylphosphoramidocyanidate (CAS 77–81–6) (CWC Schedule 1A); or

(iii) O-Alkyl (H or equal to or less than C_{10}, including cycloalkyl) S–2-dialkyl (Methyl, Ethyl, n-Propyl or Isopropyl) aminoethyl alkyl (Methyl, Ethyl, n-Propyl or Isopropyl) phosphonothiolates and corresponding alkylated and protonated salts, such as VX: O-Ethyl S–2-diisopropylaminoethyl methyl phosphonothiolate (CAS 50782–69–9) (CWC Schedule 1A);

(2) Amiton: O,O-Diethyl S-[2(diethylamino)ethyl] phosphorothiolate and corresponding alkylated or protonated salts (CAS 78–53–5) (CWC Schedule 2A);

(3) Vesicant agents, as follows:

(i) Sulfur mustards, such as: 2-Chloroethylchloromethylsulfide (CAS 2625–76–5) (CWC Schedule 1A); Bis(2-chloroethyl)sulfide (HD) (CAS 505–60–2) (CWC Schedule 1A); Bis(2-chloroethylthio)methane (CAS 63839–13–6) (CWC Schedule 1A); 1,2-bis (2-chloroethylthio)ethane (CAS 3563–36–8) (CWC Schedule 1A); 1,3-bis (2-chloroethylthio)-n-propane (CAS 63905–10–2) (CWC Schedule 1A); 1,4-bis (2-chloroethylthio)-n-butane (CWC Schedule 1A); 1,5-bis (2-chloroethylthio)-n-pentane (CWC Schedule 1A); Bis (2-chloroethylthiomethyl)ether (CWC Schedule 1A); Bis (2-chloroethylthioethyl)ether (CAS 63918–89–8) (CWC Schedule 1A);

(ii) Lewisites, such as: 2-chlorovinyldichloroarsine (CAS 541–25–3) (CWC Schedule 1A); Tris (2-chlorovinyl) arsine (CAS 40334–70–1) (CWC Schedule 1A); Bis (2-chlorovinyl) chloroarsine (CAS 40334–69–8) (CWC Schedule 1A);

(iii) Nitrogen mustards, or their protonated salts, as follows:

(A) HN1: Bis (2-chloroethyl) ethylamine (CAS 538–07–8) (CWC Schedule 1A);

(B) HN2: Bis (2-chloroethyl) methylamine (CAS 51–75–2) (CWC Schedule 1A);

(C) HN3: Tris (2-chloroethyl) amine (CAS 555–77–1) (CWC Schedule 1A); or

(D) Other nitrogen mustards, or their salts, having a propyl, isopropyl, butyl, isobutyl, or tertiary butyl group on the bis(2-chloroethyl) amine base;

Note 1 to paragraph (a)(3)(iii): Pharmaceutical formulations containing nitrogen mustards or certain reference standards for these formulations are not considered to be chemical agents and are subject to the EAR when: (1) The pharmaceutical is in the form of a final medical product; or (2) the reference standard contains salts of HN2 [bis(2-chloroethyl) methylamine], the quantity to be shipped is 150 milligrams or less, and individual shipments do not exceed twelve per calendar year per end user.

Note 2 to paragraph (a)(3)(iii): A "final medical product," as used in this paragraph, is a pharmaceutical formulation that is (1) designed for testing and administration in the treatment of human medical conditions, (2) prepackaged for distribution as a clinical or medical product, and (3) approved for marketing by the Food and Drug Administration or has a valid investigational new drug application (IND) in effect, in accordance with 21 CFR part 312.

(iv) Ethyldichloroarsine (ED) (CAS 598–14–1); or

(v) Methyldichloroarsine (MD) (CAS 593–89–5);

(4) Incapacitating agents, such as:

(i) 3-Quinuclindinyl benzilate (BZ) (CAS 6581–06–2) (CWC Schedule 2A);

(ii) Diphenylchloroarsine (DA) (CAS 712–48–1); or

(iii) Diphenylcyanoarsine (DC) (CAS 23525–22–6);

(5) Chemical warfare agents not enumerated above adapted for use in war to produce casualties in humans or animals, degrade equipment, or damage crops or the environment. (*See* the CCL at ECCNs 1C350, 1C355, and 1C395 for control of certain chemicals not adapted for use in war.)

Note to paragraph (a)(5): "Adapted for use in war" means any modification or selection (such as altering purity, shelf life, dissemination characteristics, or resistance to ultraviolet radiation) designed to increase the effectiveness in producing casualties in humans or animals, degrading equipment, or damaging crops or the environment.

Note 1 to paragraph (a): Paragraph (a) of this category does not include the following: Cyanogen chloride, Hydrocyanic acid, Chlorine, Carbonyl chloride (Phosgene), Ethyl bromoacetate, Xylyl bromide, Benzyl bromide, Benzyl iodide, Chloro acetone, Chloropicrin (trichloronitromethane), Fluorine, and Liquid pepper.

Note 2 to paragraph (a): Regarding U.S. obligations under the Chemical Weapons Convention (CWC), refer to Chemical Weapons Convention Regulations (CWCR) (15 CFR parts 710 through 721). As appropriate, the CWC schedule is provided to assist the exporter.

*(b) Biological agents and biologically derived substances and genetic elements thereof as follows:

(1) Genetically modified biological agents:

(i) Having non-naturally occurring genetic modifications that are known to or are reasonably expected to result in an increase in any of the following:

(A) Persistence in a field environment (*i.e.,* resistance to oxygen, UV damage, temperature extremes, arid conditions, or decontamination processes); or

(B) The ability to defeat or overcome standard detection methods, personnel protection, natural or acquired host immunity, host immune response, or response to standard medical countermeasures; and

(ii) Being any micro-organisms/toxins or their non-naturally occurring genetic elements as listed below:

(A) Bacillus anthracis;

(B) Botulinum neurotoxin producing species of Clostridium;

(C) Burkholderia mallei;

(D) Burkholderia pseudomallei;

(E) Ebola virus;

(F) Foot-and-mouth disease virus;

(G) Francisella tularensis;

(H) Marburg virus;

(I) Variola major virus (Smallpox virus);

(J) Variola minor virus (Alastrim);

(K) Yersinia pestis; or

(L) Rinderpest virus.

(2) Biological agent or biologically derived substances controlled in ECCNs 1C351, 1C353, or 1C354:

(i) Physically modified, formulated, or produced as any of the following:

(A) 1–10 micron particle size;

(B) Particle-absorbed or combined with nano-particles;

(C) Having coatings/surfactants, or

(D) By microencapsulation; and

(ii) Meeting the criteria of paragraph (b)(2)(i) of this category in a manner that is known to or is reasonably expected to result in an increase in any of the following:

(A) Persistence in a field environment (*i.e.,* resistant to oxygen, UV damage, temperature extremes, arid conditions, or decontamination processes);

(B) Dispersal characteristics (*e.g.,* reduced susceptibility to shear forces, optimized electrostatic charges); or protection, natural or acquired host immunity, or response to standard medical countermeasures.

Note 1 to paragraph (b): Non-naturally occurring means that the modification has not already been observed in nature, was not discovered from samples obtained from nature, and was developed with human intervention.

Note 2 to paragraph (b): This paragraph does not control biological agents or biologically derived substances when these agents or substances have been demonstrated to be attenuated relative to natural pathogenic isolates and are incapable of causing disease or intoxication of ordinarily affected and relevant species (*e.g.*, humans, livestock, crop plants) due to the attenuation of virulence or pathogenic factors. This paragraph also does not control genetic elements, nucleic acids, or nucleic acid sequences (whether recombinant or synthetic) that are unable to produce or direct the biosynthesis of infectious or functional forms of the biological agents or biologically derived substances that are capable of causing disease or intoxication of ordinarily affected and relevant species.

Note 3 to paragraph (b): Biological agents or biologically derived substances that meet both paragraphs (b)(1) and (b)(2) of this category are controlled in paragraph (b)(1).

*(c) Chemical agent binary precursors and key precursors, as follows:

(1) Alkyl (Methyl, Ethyl, n-Propyl or Isopropyl) phosphonyl difluorides, such as: DF: Methyl Phosphonyldifluoride (CAS 676–99–3) (CWC Schedule 1B); Methylphosphinyldifluoride (CAS 753–59–3) (CWC Schedule 2B);

(2) O-Alkyl (H or equal to or less than C_{10}, including cycloalkyl) O–2-dialkyl (methyl, ethyl, n-Propyl or isopropyl) aminoethyl alkyl (methyl, ethyl, N-propyl or isopropyl) phosphonite and corresponding alkylated and protonated salts, such as QL: O-Ethyl-2-di-isopropylaminoethyl methylphosphonite (CAS 57856–11–8) (CWC Schedule 1B);

(3) Chlorosarin: O-Isopropyl methylphosphonochloridate (CAS 1445–76–7) (CWC Schedule 1B);

(4) Chlorosoman: O-Pinacolyl methylphosphonochloridate (CAS 7040–57–5) (CWC Schedule 1B); or

(5) Methylphosphonyl dichloride (CAS 676–97–1) (CWC Schedule 2B); Methylphosphinyldichloride (CAS 676–83–5) (CWC Schedule 2B).

(d) [Reserved]

(e) Defoliants, as follows:

(1) 2,4,5-trichlorophenoxyacetic acid (CAS 93–76–5) mixed with 2,4-dichlorophenoxyacetic acid (CAS 94–75–7) (Agent Orange (CAS 39277–47–9)); or

*(f) Parts, components, accessories, attachments, associated equipment, materials, and systems, as follows:

(1) Any equipment for the dissemination, dispersion, or testing of articles controlled in paragraphs (a), (b), (c), or (e) of this category, as follows:

(i) Any equipment "specially designed" for the dissemination and dispersion of articles controlled in paragraphs (a), (b), (c), or (e) of this category; or

(ii) Any equipment "specially designed" for testing the articles controlled in paragraphs (a), (b), (c), (e), or (f)(4) of this category and developed under a Department of Defense contract or other funding authorization.

(2) Any equipment, containing reagents, algorithms, coefficients, software, libraries, spectral databases, or alarm set point levels developed under a Department of Defense contract or other funding authorization, for the detection, identification, warning, or monitoring of:

(i) Articles controlled in paragraphs (a) or (b) of this category; or

(ii) Chemical agents or biological agents specified in the Department of Defense contract or other funding authorization.

Note 1 to paragraph (f)(2): This paragraph does not control articles that are (a) determined to be subject to the EAR via a commodity jurisdiction determination (see § 120.4 of this subchapter), or (b) identified in the relevant Department of Defense contract or other funding authorization as being developed for both civil and military applications.

Note 2 to paragraph (f)(2): Note 1 does not apply to defense articles enumerated on the USML.

(3) [Reserved]

(4) For individual protection or collective protection against the articles controlled in paragraphs (a) and (b) of this category, as follows:

(i) M53 Chemical Biological Protective Mask or M50 Joint Service General Purpose Mask (JSGPM);

(ii) Filter cartridges containing sorbents controlled in paragraph (f)(4)(iii) or (n) of this category;

(iii) Carbon meeting MIL–DTL–32101 specifications (*e.g.*, ASZM–TEDA carbon); or

(iv) Ensembles, garments, suits, jackets, pants, boots, or socks for individual protection, and liners for collective protection that allow no more than 1% breakthrough of GD or no more than 2% breakthrough of any other chemical controlled in paragraph (a) of this category, when evaluated by

current version of Test Operating Protocols (TOPs) 08–2–201 or 08–2–501 and using the defined Department of Defense-specific requirements;

(5)–(6) [Reserved]

(7) Chemical Agent Resistant Coatings that have been qualified to military specifications (MIL–PRF–32348, MIL–DTL–64159, MIL–C–46168, or MIL–DTL–53039); or

(8) Any part, component, accessory, attachment, equipment, or system that:

(i) Is classified;

(ii) Is manufactured using classified production data; or

(iii) Is being developed using classified information.

Note to paragraph (f)(8): "Classified" means classified pursuant to Executive Order 13526, or predecessor order, and a security classification guide developed pursuant thereto or equivalent, or to the corresponding classification rules of another government.

(g) Antibodies, recombinant protective antigens, polynucleotides, biopolymers, or biocatalysts (including their expression vectors, viruses, plasmids, or cultures of specific cells modified to produce them) as follows:

(1) When exclusively funded by a Department of Defense contract for detection of the biological agents at paragraph (b)(1)(ii) of this category even if naturally occurring;

(2) Joint Biological Agent Identification and Diagnostic System (JBAIDS) Freeze Dried reagents listed by JRPD–ASY–No and Description respectively as follows:

(i) JRPD–ASY–0016 Q-Fever IVD Kit;

(ii) JRPD–ASY–0100 Vaccinia (Orthopox);

(iii) JRPD–ASY–0106 Brucella melitensis (Brucellosis);

(iv) JRPD–ASY–0108 Rickettsia prowazekii (Rickettsia);

(v) JRPD–ASY–0109 Burkholderia ssp. (Burkholderia);

(vi) JRPD–ASY–0112 Eastern equine encephalitis (EEE);

(vii) JRPD–ASY–0113 Western equine encephalitis (WEE);

(viii) JRPD–ASY–0114 Venezuelan equine encephalitis (VEE);

(ix) JRPD–ASY–0122 Coxiella burnetii (Coxiella);

(x) JRPD–ASY–0136 Influenza A/H5 IVD Detection Kit;

(xi) JRPD–ASY–0137 Influenza A/B IVD Detection Kit; or

(xii) JRPD–ASY–0138 Influenza A Subtype IVD Detection Kit;

(3) Critical Reagent Polymerase (CRP) Chain Reactions (PCR) assay kits with Catalog-ID and Catalog-ID Product respectively as follows:

Biotinylated;

(ii) PCR–BRU–1FB–K Brucella Target 1 FastBlock Master Mix;

(iii) PCR–BRU–1R–K Brucella Target 1 LightCycler/RAPID Master Mix;

(iv) PCR–BURK–2FB–B–K Burkholderia Target 2 FastBlock Master Mix Biotinylated;

(v) PCR–BURK–2FB–K Burkholderia Target 2 FastBlock Master Mix;

(vi) PCR–BURK–2R–K Burkholderia Target 2 LightCycler/RAPID Master Mix;

(vii) PCR–BURK–3FB–B–K Burkholderia Target 3 FastBlock Master Mix Biotinylated;

(viii) PCR–BURK–3FB–K Burkholderia Target 3 FastBlock Master Mix;

(ix) PCR–BURK–3R–K Burkholderia Target 3 LightCycler/RAPID Master Mix;

(x) PCR–COX–1FB–B–K Coxiella burnetii Target 1 FastBlock Master Mix Biotinylated;

(xi) PCR–COX–1R–K Coxiella burnetii Target 1 LightCycler/RAPID Master Mix;

(xii) PCR–COX–2R–K Coxiella burnetii Target 2 LightCycler/RAPID Master Mix;

(xiii) PCR–OP–1FB–B–K Orthopox Target 1 FastBlock Master Mix Biotinylated;

(xiv) PCR–OP–1FB–K Orthopox Target 1 FastBlock Master Mix;

(xv) PCR–OP–1R–K Orthopox Target 1 LightCycler/RAPID Master Mix;

(xvi) PCR–OP–2FB–B–K Orthopox Target 2 FastBlock Master Mix Biotinylated;

(xvii) PCR–OP–3R–K Orthopox Target 3 LightCycler/RAPID Master Mix;

(xviii) PCR–RAZOR–BT–X PCR–RAZOR–BT–X RAZOR CRP BioThreat-X Screening Pouch;

(xix) PCR–RIC–1FB–K Ricin Target 1 FastBlock Master Mix;

(xx) PCR–RIC–1R–K Ricin Target 1 LightCycler/RAPID Master Mix;

(xxi) PCR–RIC–2R–K Ricin Target 2 LightCycler/RAPID Master Mix; or

(xxii) PCR–VEE–1R–K Venezuelan equine encephalitis Target 1 LightCycler/RAPID Master Mix; or

(4) Critical Reagent Program Antibodies with Catalog ID and Product respectively as follows:

(i) AB–AG–RIC Aff. Goat anti-Ricin;

(ii) AB–ALVG–MAB Anti-Alphavirus Generic Mab;

(iii) AB–AR–SEB Aff. Rabbit anti-SEB;

(iv) AB–BRU–M–MAB1 Anti-Brucella melitensis Mab 1;

(v) AB–BRU–M–MAB2 Anti-Brucella melitensis Mab 2;

(vi) AB–BRU–M–MAB3 Anti-Brucella melitensis Mab 3;

(vii) AB–BRU–M–MAB4 Anti-Brucella melitensis Mab 4;

(ix) AB–CHOL–01–MAB Anti-V. cholerae 01 Mab;

(x) AB–COX–MAB Anti-Coxiella Mab;

(xi) AB–EEE–MAB Anti-EEE Mab;

(xii) AB–G–BRU–A Goat anti-Brucella abortus;

(xiii) AB–G–BRU–M Goat anti-Brucella melitensis;

(xiv) AB–G–BRU–S Goat anti-Brucella suis;

(xv) AB–G–CHOL–01 Goat anti-V.cholerae 0:1;

(xvi) AB–G–COL–139 Goat anti-V.cholerae 0:139;

(xvii) AB–G–DENG Goat anti-Dengue;

(xviii) AB–G–RIC Goat anti-Ricin;

(xix) AB–G–SAL–T Goat anti-S. typhi;

(xx) AB–G–SEA Goat anti-SEA;

(xxi) AB–G–SEB Goat anti-SEB;

(xxii) AB–G–SEC Goat anti-SEC;

(xxiii) AB–G–SED Goat anti-SED;

(xxiv) AB–G–SEE Goat anti-SEE;

(xxv) AB–G–SHIG–D Goat anti-Shigella dysenteriae;

(xxvi) AB–R–BA–PA Rabbit anti-Protective Antigen;

(xxvii) AB–R–COX Rabbit anti-C. burnetii;

(xxviii) AB–RIC–MAB1 Anti-Ricin Mab 1;

(xxix) AB–RIC–MAB2 Anti-Ricin Mab 2;

(xxx) AB–RIC–MAB3 Anti-Ricin Mab3;

(xxxi) AB–R–SEB Rabbit anti-SEB;

(xxxii) AB–R–VACC Rabbit anti-Vaccinia;

(xxxiii) AB–SEB–MAB Anti-SEB Mab;

(xxxiv) AB–SLT2–MAB Anti-Shigella-like t x2 Mab;

(xxxv) AB–T2T–MAB1 Anti-T2 Mab 1;

(xxxvi) AB–T2T–MAB2 Anti-T2 Toxin 2;

(xxxvii) AB–VACC–MAB1 Anti-Vaccinia Mab 1;

(xxxviii) AB–VACC–MAB2 Anti-Vaccinia Mab 2;

(xxxix) AB–VACC–MAB3 Anti-Vaccinia Mab 3;

(xl) AB–VACC–MAB4 Anti-Vaccinia Mab 4;

(xli) AB–VACC–MAB5 Anti-Vaccinia Mab 5;

(xlii) AB–VACC–MAB6 Anti-Vaccinia Mab 6;

(xliii) AB–VEE–MAB1 Anti-VEE Mab 1;

(xliv) AB–VEE–MAB2 Anti-VEE Mab 2;

(xlv) AB–VEE–MAB3 Anti-VEE Mab 3;

(xlvi) AB–VEE–MAB4 Anti-VEE Mab 4;

(xlvii) AB–VEE–MAB5 Anti-VEE Mab 5;

(xlviii) AB–VEE–MAB6 Anti-VEE Mab 6; or

(h) Vaccines exclusively funded by a Department of Defense contract, as follows:

(1) Recombinant Botulinum Toxin A/B Vaccine;

(2) Recombinant Plague Vaccine;

(3) Trivalent Filovirus Vaccine; or

(4) Vaccines specially designed for the sole purpose of protecting against biological agents and biologically derived substances identified in paragraph (b) of this category.

Note to paragraph (h): See ECCN 1A607.k for military medical countermeasures such as autoinjectors, combopens, and creams.

(i) Modeling or simulation tools, including software controlled in paragraph (m) of this category, for chemical or biological weapons design, development, or employment developed or produced under a Department of Defense contract or other funding authorization (*e.g.,* the Department of Defense's HPAC, SCIPUFF, and the Joint Effects Model (JEM)).

(j)–(l) [Reserved]

(m) Technical data (as defined in § 120.10 of this subchapter) and defense services (as defined in § 120.9 of this subchapter) directly related to the defense articles enumerated in paragraphs (a) through (l) and (n) of this category. (*See* § 125.4 of this subchapter for exemptions.)

(n) Developmental countermeasures or sorbents funded by the Department of Defense via contract or other funding authorization;

Note 1 to paragraph (n): This paragraph does not control countermeasures or sorbents that are (a) in production, (b) determined to be subject to the EAR via a commodity jurisdiction determination (see § 120.4 of this subchapter), or (c) identified in the relevant Department of Defense contract or other funding authorization as being developed for both civil and military applications.

Note 2 to paragraph (n): Note 1 does not apply to defense articles enumerated on the USML, whether in production or development.

Note 3 to paragraph (n): This paragraph is applicable only to those contracts and funding authorizations that are dated July 28, 2017, or later.

(o)–(w) [Reserved]

(x) Commodities, software, and technology subject to the EAR (see § 120.42 of this subchapter) used in or with defense articles controlled in this category.

Note to paragraph (x): Use of this paragraph is limited to license applications for defense articles controlled in this category where the purchase documentation includes commodities, software, or technology subject to the EAR (see § 123.1(b) of this subchapter).

* * * * *

Category XVIII—Directed Energy Weapons

* (a) Directed energy weapons as follows:

(1) Systems or equipment that, other than as a result of incidental, accidental, or collateral effect:

(i) Degrade, destroy or cause mission-abort of a target;

(ii) Disturb, disable, or damage electronic circuitry, sensors or explosive devices remotely;

(iii) Deny area access;

(iv) Cause lethal effects; or

(v) Cause ocular disruption or blindness; and

(2) Use any non-acoustic technique such as lasers (including continuous wave or pulsed lasers), particle beams, particle accelerators that project a charged or neutral particle beam, high power radio-frequency (RF), or high pulsed power or high average power radio frequency beam transmitters.

*(b) Systems or equipment specially designed to detect, identify, or provide defense against articles specified in paragraph (a) of this category.

(c)–(d) [Reserved]

(e) Components, parts, accessories, attachments, systems or associated equipment specially designed for any of the articles in paragraphs (a) or (b) of this category.

(f) Developmental directed energy weapons funded by the Department of Defense via contract or other funding authorization, and specially designed parts and components therefor;

Note 1 to paragraph (f): This paragraph does not control directed energy weapons (a) in production, (b) determined to be subject to the EAR via a commodity jurisdiction determination (see § 120.4 of this subchapter), or (c) identified in the relevant Department of Defense contract or other funding authorization as being developed for both civil and military applications.

Note 2 to paragraph (f): Note 1 does not apply to defense articles enumerated on the USML, whether in production or development.

Note 3 to paragraph (f): This paragraph is applicable only to those contracts and funding authorizations that are dated July 28, 2017, or later.

(g) Technical data (see § 120.10 of this subchapter) and defense services (as defined in § 120.9 of this subchapter) directly related to the defense articles enumerated in paragraphs (a) through (e) of this category;

(x) Commodities, software, and technology subject to the EAR (see § 120.42 of this subchapter) used in or with defense articles controlled in this category.

Note to paragraph (x): Use of this paragraph is limited to license applications for defense articles controlled in this category where the purchase documentation includes commodities, software, or technology subject to the EAR (see § 123.1(b) of this subchapter).

Rose E. Gottemoeller,

Under Secretary, Arms Control and International Security, Department of State.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 33

[EPA–HQ–OA–2006–0278; FRL–9946–27–OA]

RIN 2090–AA40

Participation by Disadvantaged Business Enterprises in Procurements Under EPA Financial Assistance Agreements

AGENCY: Environmental Protection Agency.

ACTION: Direct final rule.

SUMMARY: Environmental Protection Agency (EPA) is taking direct final action on revisions to the EPA's Disadvantaged Business Enterprise (DBE) program. We are approving these revisions to improve the practical utility of the program, minimize burden, and clarify requirements that have been the subject of questions from recipients of EPA financial assistance and from disadvantaged business enterprises. These revisions are in accordance with the requirements of the Federal laws that govern the EPA DBE program.

DATES: This rule is effective on October 26, 2016 without further notice, unless EPA receives adverse comment by August 29, 2016. If EPA receives adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OA–2006–0278, at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Teree Henderson, Office of the Administrator, Office of Small Business Programs (mail code: 1230A), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: 202–566–2222; fax number: 202–566–0548; email address: *henderson.teree@epa.gov.*

SUPPLEMENTARY INFORMATION:

Acronyms and Abbreviations. The following acronyms and abbreviations are used in this document.

BCRLF	Brownfields Cleanup Revolving Loan Fund
CWSRF	Clean Water State Revolving Fund
DWSRF	Drinking Water State Revolving Fund
EDWOSB	Economically Disadvantaged Woman Owned Small Business Program
DOT	Department of Transportation
SBA	Small Business Administration
DBE	Disadvantaged Business Enterprise
MBE	Minority Business Enterprise
WBE	Women's Business Enterprise
EPA	Environmental Protection Agency
OSBP	Office of Small Business Programs
SBVPS	Small Business Vendor Profile System

I. Why is EPA using a direct final rule?

EPA is publishing this rule without a prior proposed rule because we view this as a noncontroversial action and anticipate no adverse comments. The actions are intended to improve the practical utility of the program, minimize burden, and clarify requirements that have been the subject of questions from recipients of EPA financial assistance and from disadvantaged business enterprises. However, in the ''Proposed Rules'' section of this **Federal Register**, we are publishing a separate document that will serve as the proposed rule to amend these regulations, if EPA receives signification adverse comments on this direct final rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. For further information about commenting on this rule, see the **ADDRESSES** section of this document.

If EPA receives adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that this direct final rule will not take effect. We will address all public comments in any subsequent final rule based on the proposed rule.

II. Does this action apply to me?

If you are a recipient of an EPA financial assistance agreement; an entity receiving an identified loan under a financial assistance agreement capitalizing a revolving loan fund; or a minority-owned, woman-owned, or small business, this rule may affect you. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

III. What should I consider as I prepare my comments for EPA?

A. Submitting CBI. Do not submit this information to EPA through *www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI). In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

B. Tips for Preparing Your Comments. When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

IV. Background

The EPA's DBE Program is implemented through 40 CFR part 33, which was promulgated on March 26, 2008 (73 FR 15904) (hereafter referred to as "part 33"). The DBE program arose out of a review of affirmative action programs in the federal government following the Supreme Court's decision in *Adarand Constructors, Inc.* v. *Federico Pena, Secretary of Transportation,* 515 U.S. 200. The rule sets forth a narrowly tailored EPA program that serves the compelling government interest of remedying past and current racial discrimination, by establishing agency-wide DBE procurement objectives.

The DBE Program has four major components designed to ensure that minority and women-owned businesses have the opportunity to participate in procurements funded by EPA financial assistance agreements. These components are as follows:

- *DBE Certification:* The current DBE Program requires that in order to be counted as an MBE or WBE under an EPA financial assistance agreement, an entity will have to be certified as such. The EPA requires an MBE/WBE to first seek certification by a federal agency (*e.g.,* the Small Business Administration (SBA), the Department of Transportation (DOT)), or by a State, locality, Indian Tribe, or independent private organization provided their applicable criteria match those under section 8(a)(5) and (6) of the Small Business Act and SBA's applicable 8(a) Business Development Program regulations. The EPA then provides for certification of firms that cannot get certified by one of these entities. The EPA certification program provides an option for businesses that may not fall into a classification that is certified by other sources and provides for these businesses to participate in EPA's DBE program.
- *Negotiating Fair Share Goals:* The current DBE program requires all recipients of EPA financial assistance agreements to negotiate goals with the Agency for the utilization of MBEs/WBEs for procurements funded by EPA financial assistance agreements. The goals are based on disparity studies or availability analyses showing the availability of MBEs or WBEs in the financial assistance recipient's relevant geographic buying market. These goals do not operate as quotas.
- *Using the "Good Faith Efforts":* The "Good Faith Efforts" are measures implored by all EPA financial assistance agreement recipients to ensure that all DBEs have the opportunity to compete for procurements funded by EPA financial assistance dollars, and contain measures a financial assistance recipient may undertake to make procurements more open to MBEs and WBEs.
- *Reporting Accomplishments:* Under the current DBE program, recipients of EPA financial assistance agreements are required to report on their accomplishments with the program using EPA Form 5700–52A. Reporting is the tool the EPA uses to assess whether or not the program is effective and actually translating into increased opportunities for MBEs and WBEs.

When the final rule was promulgated, the EPA stated that the agency will "evaluate the propriety of the Disadvantaged Business Enterprise program in 7 years through subsequent rulemaking" (73 FR 15904). On August 13, 2013, OMB approved the information collection request supporting the DBE Program with the following Terms of Clearance: "This ICR is approved for a period of 2 years until 2015, when EPA will undertake a comprehensive review of the Disadvantaged Business Enterprise rule." The EPA Office of Small Business Programs (OSBP) has subsequently worked collaboratively with various program offices within the Agency and EPA regional DBE coordinators through various face-to-face meetings and conference calls from May–December 2014.

V. Summary of Changes

The EPA is amending subparts A through E of part 33 to improve the practical utility of the EPA's DBE program and minimize the burden to affected entities. The EPA made three major revisions in the rule that will significantly impact the way the DBE program currently operates. These changes, which are described in detail in section IV of this preamble, include:

1. Establishing a self-certification platform for MBEs and WBEs. The EPA removed existing EPA certification requirements in subpart B of part 33 for firms that cannot be certified by another federal agency, and will instead allow qualified firms to self-certify as an MBE or WBE.

2. Updating the exemption threshold for fair share negotiations. The EPA increased the threshold for recipients exempted from negotiating fair share objectives in subpart D of part 33 from $250,000 to $1 million.

3. Revising the reporting frequency and applicability. The EPA revised subpart E of part 33 to change the frequency of DBE reporting to annual for all recipients, and limit reporting to financial assistance agreements with funds budgeted for procurements above the simplified acquisition threshold of $150,000.

In addition to these changes, the EPA made minor changes to part 33 to minimize information collection, clarify requirements, update references, and harmonize requirements with uniform administrative requirements published by the Office of Management and Budget (OMB).

VI. Detail and Rationale for Changes

Additional details for the revisions to subparts A through E of part 33 and the rationale for these revisions are described respectively in the sections below.

A. Subpart A—General Provisions

The EPA has made several changes to the General Provisions (subpart A) of part 33 to clarify the objectives, applicability, and implementation procedures of the DBE Program. The changes are intended primarily to clarify the requirements that apply to recipients and will not impose any new requirements or burdens that do not already exist.

First, we changed the first statement of DBE program objectives in 40 CFR 33.101(a) from: "To ensure nondiscrimination in the award of contracts under EPA assistance agreements" to: "To foster nondiscrimination in the award and administration of procurements under EPA financial assistance agreements". The purpose of this change is to clarify that the program is not limited to particular types of procurements by a recipient of EPA financial assistance (*e.g.*, only to contracts issued), but applies to all goods or services procured by a recipient under any type of financial instrument.

Second, we clarified to whom the requirements of part 33 apply. We changed the title of 40 CFR 33.102 to "To Whom Does This Part Apply?". The EPA further amended the text to specify that part 33 applies to recipients of any of four different types of financial assistance agreements issued by the EPA, which are as follows: EPA financial assistance agreements, grants, or cooperative agreements used to capitalize revolving loan funds, Special Appropriations Act Projects, and subawards from an EPA recipient of any such funds. The revision still specifies that part 33 does not apply to work that is conducted outside the United States or its territories and insular possessions, or that is not funded under an EPA financial assistance agreement. Next, the EPA updated the definitions of terms in 40 CFR 33.103. One goal of the revisions to part 33 incorporates the principles established by 2 CFR part 200—Uniform Administrative Requirements, Cost Principles, And Audit Requirements for Federal Awards (hereafter referred to as "part 200"). Part 200 was finalized on October 9, 2015, and supersedes a number of OMB circulars governing the administration of federal financial awards. The reforms adopted by part 200 were intended (1) to streamline OMB guidance for the administration of financial awards to ease burden, and (2) to strengthen oversight of federal awards to increase efficiency and effectiveness of the awards. The rule applies both to federal agencies that issue financial assistance, encompassing the types of financial assistance provided by the EPA, and to recipients of the awards. We made minor amendments throughout Part 33 to incorporate these changes. In 40 CFR 33.104, we amended and added several definitions to be consistent with part 200, as well as update the introduction to the section to state that terms not defined in Part 33 will have the meaning given to them in part 200.

We also consolidated several existing definitions in 40 CFR 33.104. For example, we added the term "procurement" as "the acquisition of goods and services under a financial assistance agreement as defined by applicable regulations for the particular type of financial assistance received". The term encompasses all forms of procurement and will replace the current definitions for "construction", "equipment", "services", and "supplies" in subpart A and throughout part 33. To improve readability, we consolidated the definitions of all terms in Part 33 into subpart A by moving all the terms that are defined in 40 CFR part 33, subparts B, C, D, and E into 40 CFR 33.103. For example, we revised 40 CFR 33.202 and 33.303 to move the definitions of "ownership or control," "socially disadvantaged individual", and "economically disadvantaged individual" to 40 CFR 33.103. Also, we amended certain definitions to be consistent with the rules of the Small Business Administration (13 CFR part 124) Department of Transportation (DOT) DBE Program, and Title X of the Clean Air Act Amendments of 1990 (42 U.S.C. 7601 note), as well as to add minor clarifications.

The EPA also made changes to the provisions of 40 CFR 33.104 for recipients to obtain a waiver from any of the requirements of part 33. We made a substantive change that will place a 5 year limitation on the duration of each waiver and a recipient will need to reapply for the waiver at least 60 days prior to the expiration date. Previously, waivers were granted for "a reasonable duration" to be determined by the Director of the Office of Small and Disadvantaged Business Utilization, and could be terminated at any time at the Director's discretion. Providing specific time frames for waiver duration ensures equity and consistency in issuing waivers across all recipients. The rule also changes the title of Director of the Office of Small and Disadvantaged Business Utilization to Director of Small Business Programs to reflect current EPA organizational structure. We made similar harmonizing changes throughout part 33 to update all references to the Office of Small and Disadvantaged Business Utilization (OSDBU) to the Office of Small Business Programs (OSBP).

The rule also revises 40 CFR 33.105, "What are the compliance and enforcement provisions of this part?" to more clearly parallel the applicable noncompliance remedies available to the EPA under regulations of the Office of Management and Budget for federal awards in 2 CFR 200.338. We changed a reference in 40 CFR 33.105 from 2 CFR part 200 to the more specific applicable reference of 2 CFR 200.338, and to edit the list of examples of remedial actions in 40 CFR 33.105 to be identical to the examples provided in 2 CFR 200.338. The EPA incorporated a new requirement into 40 CFR 33.107 for recordkeeping and records access. We incorporated by reference the recordkeeping and records access provisions of 2 CFR 200.33 through 200.337. These provisions, in general, require recipients of federal awards to retain all records that are relevant to the award for a period of 3 years and to allow the government access to the records for purposes of auditing. These changes are part of the EPA's effort to update part 33 to incorporate the principles established by part 200, as described in section IV.1 of this preamble. Finally, we revised appendix A to part 33. First, we revised appendix A from an appendix of part 33 (following subpart E) to an appendix of the General Provisions. The term and condition of appendix A is a reference of the requirements of 40 CFR 33.106; therefore, including the term and condition as an appendix of subpart A improves the readability of the subpart. We also amended appendix A to add the additional stipulation that any procurement contract signed by a recipient must include the contract provisions of 2 CFR part 200, appendix II. Appendix II clarifies all of the contract provisions that are required by other applicable statutes and regulations for contracts issued by recipients of federal financial assistance. The requirement to comply with appendix II is not a new requirement but adding this stipulation in appendix A to part 33 makes the requirement clearer to recipients and reduces the risk of unintentional noncompliance.

B. Subpart B—Certification

The rule will implement several significant changes to the existing certification requirements of subpart B of part 33. First, the EPA revised the certification requirements of 40 CFR 33.204 through 33.211 to revise the EPA's existing certification process for firms that cannot be certified by another federal agency. Under the current requirements of part 33, the EPA requires an MBE or WBE to first seek certification by a federal agency (*e.g.*, the Small Business Administration (SBA), the Department of Transportation (DOT)), or by a State, locality, Indian Tribe, or independent private organization (provided their applicable criteria match those under section 8(a)(5) and (6) of the Small Business Act and SBA's applicable 8(a) Business Development Program regulations). The EPA only considers certifying firms that cannot get certified by one of these entities. The EPA has previously required firms to first seek certification from other sources because an EPA certification is limited in that it is only accepted for opportunities funded by EPA financial assistance agreements. Conversely, certifications from other sources are beneficial for the business entity because they have broader applications. In implementing the DBE program over the past seven years, the EPA has received applications from various entities requesting EPA certification of their MBE/WBE status. For an EPA certification, the current rule requires that entities submit a paper application with evidence demonstrating that the entity meets the requirements of 40 CFR 33.202 and 33.203 (*i.e.*, the entity is owned or controlled by one or more individuals claiming disadvantaged status under the EPA's 8 percent statute or owned and controlled by one or more individuals claiming disadvantaged status under the EPA's 10 percent statute), along with evidence regarding the disadvantaged status of such individuals and documentation of a denial of certification from another certifying entity. The application is then evaluated according to by the EPA within 30 days for approval. A review of this process, including the applications that the EPA has approved or denied for certification, determined that the overall demand for EPA certification has been nominal. In addition, the majority of firms seeking an EPA certification under 40 CFR 33.205 were already certified under other programs, and further EPA certification was unnecessary. Further, the current process, including the period for EPA review, is resource intensive and extends the time in which a facility receives its certification. For these reasons, the EPA removed the existing EPA certification requirements in 40 CFR 33.205 and will no longer processes paper applications.

In lieu of the current application and evaluation requirements, revised 40 CFR 33.204 and 33.205 to accept and implement a self-certification process for firms who are not otherwise certified by another entity. The requirements will allow qualified firms to self-certify under the EPA's DBE program as an MBE or WBE, using the EPA's Small Business Vendor Profile System (SBVPS). Under this approach, firms seeking an EPA certification will register in the online SBVPS. Registration in the SBVPS will require the firm to provide their firm name and contact information, federal tax ID, DUNS no., type of business, date of start, annual sales, company size and classification, ethnicity, any other prior certifications. Firms will then self-attest to meeting the eligibility requirements set forth in 40 CFR 33.202 and 33.203. The self-certification provided through the SBVPS will be legally-binding. This approach, which is consistent with the certification requirements of other federal agencies including the SBA, does not require submittal of additional information, or require EPA review of an application. However, the EPA could request entities to provide evidence that they meet the eligibility requirements at any time. These self-certification requirements will reduce burden on firms by removing the current paper application process and decreasing the time spent by entities acquiring certification. These changes will also streamline agency activities related to maintaining forms, conducting reviews, and responding to applicants, resulting in an overall burden reduction.

The approach will no longer require businesses to first seek certification from other entities before requesting EPA DBE certification. All businesses who meet the EPA DBE program certification requirements will be able to participate in self-certifying. The EPA will still accept certifications from other sources, including a federal agency, state, locality, Indian Tribe, or independent private organization, provided their standards for certification meet or exceed the EPA's. The EPA DBE self-certification will also remain only applicable to opportunities funded by EPA financial assistance agreements; 40 CFR 33.405 will clarify that the EPA's DBE certification will be not recognized by other federal, state or local organizations. Therefore, the EPA will continue to encourage businesses to obtain certifications from these sources. The self-certification approach will also provide for proof of certification for such facilities under EPA's DBE program. We revised 40 CFR 33.206 to provide for firms who self-certify through the SBVPS to be listed on the EPA's SBVPS through the OBSP Web site. The list will be publically available and provide assurance to recipients of EPA funding that the entities listed are certified and eligible for participation.

Similar to the existing EPA certification, EPA self-certifications under this new approach will be valid for a period of three years. We revised 40 CFR 33.207 to specify that this period will begin from the date an entity is self-certified in the EPA's SBVPS. The SBVPS database will automatically purge data every three years, therefore firms will be required to re-register every three years to maintain their MBE or WBE status. Because facilities will be responsible for their registration and are self-certifying, we removed the requirements of 40 CFR 33.207, 33.209, and 33.211, which apply to re-application, re-evaluation, and appeal of EPA determinations for certified entities. We also revised 40 CFR 33.210 to clarify that facilities are responsible for keeping the EPA informed of any changes which may affect the entity's certification, including requiring the entity to remove its self-certification from the SBVPS database within 30 days of any changes to its eligibility status. This timeline is consistent with current requirements. The EPA also made several minor revisions to subpart B of Part 33 that will clarify existing requirements or provide for additional flexibility for affected entities. As discussed in section IV.1 of this preamble, we consolidated the definitions for "ownership or control," "socially disadvantaged individual", and "economically disadvantaged individual" in 40 CFR 33.202 and 33.203 under subpart A of part 33. We removed the definitions for "HBCU" and "Women" in paragraphs (d) and (e) of 40 CFR 33.203; the definition of "HBCU" is already included in 40 CFR 33.103, and a specific definition for "Women" is no longer necessary as women are included within the definitions for "socially disadvantaged individual" and "economically disadvantaged individual."

We made several clarifications to 40 CFR 33.204, including clarifying the content by revising the title to read "What certifications are acceptable for establishing MBE or WBE status under the EPA DBE Program?" We also clarified the rule references for those outside certifications currently accepted by the EPA (*e.g.,* the SBA's 8(a) Business Development Program or its Small Disadvantaged Business (SDB) Program), and adding a reference to the Economically Disadvantaged Woman Owned Small Business (EDWOSB) Program (13 CFR part 127, subpart B). The EDWOSB was established on Oct. 7, 2010 (75 FR 62282) and provides certification requirements that meet or exceed the EPA's standards; the change will benefit entities by providing an additional certification option. Finally, we are clarifying that the certifications under the United States Department of Transportation (DOT) Participation by Disadvantaged Business Enterprises in DOT Programs are acceptable only with U.S. citizenship. The change clarifies that the existing U.S. citizenship requirement under Part 33 applies to these certifications.

C. Subpart C—Good Faith Efforts

The EPA made several changes to the Good Faith Efforts requirements of subpart C of 40 CFR part 33 to clarify the requirements. The revisions will not impose any new requirements or burdens, but primarily reorganizes the subpart in a more logical order to make the goals and obligations more apparent. We made one change to reduce burden.

We made several changes to 40 CFR 33.301. First, we replaced the introduction to 40 CFR 33.301 ("What does this subpart require?") with a statement of purpose to clarify that good faith efforts are methods used by EPA recipients to ensure that DBEs have the opportunity to compete for procurements funded by EPA financial assistance dollars. A new paragraph (h) will consolidate in one place and clarify the actions that constitute good faith efforts. Paragraph (h) is a result of reorganization and will not change any existing requirements. For example, we codified that recipients must use the services of available minority/women community organizations; minority/women contractors' groups; local, state, and Federal minority/women business assistance offices; and other organizations, when feasible, when conducting the good faith efforts. This requirement is based on the existing good faith efforts, as outlined in the July 24, 2003 proposed DBE rule (68 FR 43824). We made one minor harmonizing change to 40 CFR 33.408 for consistency.

The rule will also add several new paragraphs to 40 CFR 33.301 to clarify the administrative requirements for meeting the good faith efforts. First, we are adding new text in paragraphs (b) and (c) to clarify that no recipients are exempted from the good faith efforts requirements, including recipients that are exempt from the fair share objectives of 40 CFR part 33, subpart D. We also added a new paragraph (e) to clarify that recipients are required to ensure that all sub-recipients/prime contractors meet these requirements. These stipulations are inferred in the current provisions but were added to 40 CFR 33.301 for clarity. The changes to 40 CFR 33.301 will also clarify that subpart C does not negate the post federal award requirements of part 200.

We also clarified in 40 CFR 33.301(d) that recipients must retain records of the methods used to adhere to good faith efforts. This provision already is required by the existing recordkeeping requirements of 40 CFR 33.501(a), but was added to 40 CFR 33.301(d) for clarity and better organizational placement. In a related change, we added a new paragraph (i) to clarify what constitutes non-compliance with subpart C. Paragraph (i) specifies that recipients that fail to meet all the fair share goals will not be penalized if they document the circumstances that prohibited full execution of each requirement, but that failure to retain proper documentation may constitute noncompliance.

Next, for 40 CFR 33.302 ("Are there any additional contract administration requirements?"), we reduced a reporting requirement by eliminating Form 6100–2. Under the current rule, prime contractors are required to provide Form 6100–2 to DBE subcontractors. Form 6100–2 is an optional form that gives a DBE subcontractor the opportunity to inform the EPA about the work received and/or report any concerns regarding the EPA-funded project (*e.g.,* termination by prime contractor, late payments, et al.). We are eliminating this form because the EPA has no legal authority or other leverage to intervene on behalf of the DBE to resolve any such problems. Eliminating this form will not hinder effective implementation of the program, but will reduce burden on recipients, prime contractors, DBEs, and the EPA. We also added a stipulation to 40 CFR 33.302 that failure to include EPA Forms 6100–3 and 6100–4 may constitute non-responsiveness and that the recipient may consider this non-responsiveness in evaluating a prime contractor's proposal. Forms 6100–3 and 6100–4 document the intended degree of DBE utilization under any prime contract issued by the recipient. This change is intended to provide clarification of compliance under subpart C and does not change any existing requirements. To ensure that a recipient is aware of all required contracting provisions, text was added to point out that all procurement contracts awarded by a recipient must contain the provisions specified in 2 CFR part 200, appendix II, as applicable.

We made one editorial correction to 40 CFR 33.303 ("Are there special rules for loans under EPA financial assistance agreements?") by changing the clause beginning with "such as . . ." to "including but not limited to . . ." so that the clause clarifies but does not limit applicability of the section.

Finally, we clarified 40 CFR 33.304 to more accurately reflect the contents of the provisions and to clarify that a Native American recipient includes a consortium. The title will be "What special rules apply to a Native American (either as an individual, organization, Tribe or Tribal Government or consortium) Recipient or Prime Contractor when following the six good faith efforts?" We also made a harmonizing change to 40 CFR 33.304(a).

D. Subpart D—Fair Share Objectives

The EPA made revisions to subpart D of part 33 to revise the requirements for recipients of EPA financial assistance agreements to negotiate fair share objectives for MBE and WBE participation. The changes will generally reduce burden for recipients by reducing the number of recipients required to negotiate fair share objectives or revising the information that must be submitted by recipients. We also provided additional clarifications and harmonizing changes that will not impose any new requirements or burdens that do not already exist.

First, the EPA revised 40 CFR 33.401 and 33.402 to clarify that in addition to negotiating its own fair share objectives, a recipient may use the approved fair share objective of another recipient with the same or similar relevant geographic buying market, purchasing the same or similar items. The EPA made one related harmonizing change to 40 CFR 33.405(a). These amendments harmonizes the requirements for recipients of EPA financial assistance agreements and financial agreements to capitalize revolving loan funds with the existing requirements of 40 CFR 33.405(b)(3), which allow recipients to use the fair share objectives of another recipient when determining a base figure for the relative availability of MBEs and WBEs. The EPA also revised 40 CFR 33.402 to clarify that for loan procurements that will occur over more than one year, the recipient should apply the fair share objectives in place to the year in which the procurement action occurs. Previously, the recipient could choose to apply the fair share objective in place either for the year in which the identified loan was awarded or for the year in which the procurement action occurred. These two options resulted in frequent questions from recipients; the change implements the former option and provides a consistent approach for all recipients.

We made one minor revision to 40 CFR 33.403 ("What is a fair share objective?") to remove the categories of construction, equipment, services and supplies, consistent with the changes to the definition of "procurement" discussed in section IV.1 of this preamble.

Next, we revised the timeline for submittal of proposed fair share objectives and the EPA's subsequent review schedule. Specifically, we made revisions to 40 CFR 33.404 to shorten the time for recipients to submit their proposed MBE and WBE fair share objectives from 120 days to 90 days after acceptance of a financial assistance award. Because MBE and WBE fair share objectives must be agreed upon by the recipient and EPA before funds may be expended for procurement, the EPA has determined that recipients must submit their fair share objectives sooner in order to ensure that projects are commenced in a timely manner. These revisions will affect only those recipients that exceed the exemption threshold in 40 CFR 33.411. We also revised the timeframe for the EPA to respond in writing to the recipient's submission from 30 days to 45. We included these extra 15 days because the agency typically reviews a high number of applicants at one time. This time frame still allows for projects to commence earlier, as the rule provides that if EPA does not provide a response within 45 days then the fair share objectives submitted by the recipient are automatically agreed upon.

We made two substantive revisions to 40 CFR 33.405, which provides for how recipients must determine MBE and WBE fair share objectives. First, we made revisions to 40 CFR 33.405(a) to require recipients to propose two separate MBE and WBE fair share objectives. Under the current rule, recipients are required to determine separate MBE and WBE fair share objectives for each of the four procurement categories, with the option to combine the four categories into one weighted objective. The revision is a harmonizing change with the changes to the definition of "procurement" discussed in section IV.1 of this preamble, which removes the four procurement categories from part 33. The revisions will significantly reduce the burden required of recipients by reducing the number of fair share objectives that must be determined. We made related minor harmonizing changes to 40 CFR 33.405(b)(1) and (2). Additionally, we made revisions to 40 CFR 33.405(c) to clearly state the applicable noncompliance remedies available to the EPA for recipients that fail to determine and implement fair share objectives. The rule references the applicable remedies under OMB regulations for federal awards in 2 CFR 200.338, including the specific applicable reference of 2 CFR 200.338, and the list of examples provided in 2 CFR 200.338. The EPA made the same changes to 40 CFR 33.410 to clarify the remedial actions that may be taken when a recipient fails to meet the requirements of subpart D.

The EPA made amendments to 40 CFR 33.407 to revise the length of the period that a recipient's negotiated fair share objectives are effective from 3 fiscal years to 5 fiscal years. The increase reflects the typical award period for grants, which are 3 to 5 years in length. By increasing the period for which fair share objectives are effective to five years, the change eliminates the possibility of a grant recipient having to renegotiate its fair share objectives midway through a project. This revision reduces the burden on recipients by reducing the frequency and time needed to revise their objectives.

We made a significant change to 40 CFR 33.411 to revise the exemption threshold for recipients required to meet the fair share objectives of subpart D. Currently, recipients of any single EPA financial assistance agreement in the amount of $250,000 or less or recipients of more than one EPA financial assistance agreement with a combined total of $250,000 or less in any one fiscal year is not required to apply the fair share objective requirements. In its implementation of the DBE program, the EPA has received feedback from stakeholders receiving smaller financial assistance rewards regarding the burden associated with collecting data for the determination of fair share objectives. Typically, the recipients of funding awards totaling in an amount lesser than $1 million are smaller entities who have very limited resources and personnel available to collect directory and census bureau data, perform disparity studies, develop alternative methods, or collect evidence from related fields or recipients to calculate the fair share goals. Given these limitations, such recipients have expressed difficulty in meeting the fair share objectives in a timely manner to guarantee funding of the assistance agreement. In such cases, these recipients have been unable to take advantage of the awarded funds and experienced delays or failures in completing EPA projects. In order to reduce the burden for these recipients and ensure that these smaller entities are able to expend funds under their awarded financial assistance agreement, we revised the exemption threshold from $250,000 to $1 million. The EPA identified a new threshold of $1 million based on a review of funding awarded to all entities during implementation of the program. Through this review, the EPA determined that the majority of funding award by the EPA (over 90 percent) is allotted to larger entities who received financial assistance agreements of greater than $1 million or a combination of financial assistance agreements whose total exceeds $1 million. Therefore, the EPA determined that a $1 million threshold will provide relief for smaller entities while ensuring that those recipients that receive the majority of funding from financial assistance agreements awarded by the EPA will continue to develop fair share objectives. These larger entities typically have the resources and personnel to conduct the data gathering steps required for development of the fair share goals. As such, the new threshold will ensure that for the majority of financial assistance agreements awarded by the EPA, recipients will continue to set goals for MBE and WBE participation in procurement.

The EPA made additional minor revisions to 40 CFR 33.411. We revised 40 CFR 33.411(b) to clarify that the recipients of loans other than loans from the Clean Water State Revolving Fund (CWSRF) Program, Drinking Water State

Revolving Fund (DWSRF) Program, and Brownfields Cleanup Revolving Loan Fund (BCRLF) Program who are below the exemption threshold of $1 million are not required to meet the fair share objective requirements of subpart D. We also revised 40 CFR 33.411(c) to clarify the reference for Performance Partnership Grants (PPGs) and to consolidate the requirements of 40 CFR 33.412. We removed 40 CFR 33.412 and revised 40 CFR 33.411 to include all exemptions to the fair share objectives in one place. Finally, we revised the term "grant" to "assistance agreement" in 40 CFR 33.411(c) to clarify that the exemptions apply to recipients of annual assistance agreements other than grants.

E. Subpart E—Recordkeeping and Reporting

The EPA made one significant change and several minor clarifications to the recordkeeping and reporting requirements of subpart E of part 33. Notably, we revised the reporting requirements of 40 CFR 33.502 to incorporate a Class Deviation previously issued by the EPA to grant exceptions from the reporting requirements of Part 33 (hereafter referred to as the "Deviation"). The Deviation changed the frequency of DBE reporting in 40 CFR 33.502 to annual for all recipients, and limited reporting to financial assistance agreements with funds budgeted for procurements above the simplified acquisition threshold. Specifically, the Deviation established that recipients, including recipients of financial assistance agreements that capitalize revolving loan programs, are required to report MBE/WBE participation annually on EPA Form 5700–52A when one or more of the following conditions are met: (1) There are funds budgeted for procurements, including funds budgeted for direct procurement by the recipient or procurement under sub-awards or loans in the "Other" category that exceed the simplified acquisition threshold amount of $150,000; (2) if at the time of award the budgeted funds for procurement exceed $150,000, but actual expenditures fall below, or; (3) if subsequent amendments and funding cause the total amount of procurement to surpass the $150,000 threshold. The Deviation also directed that where reporting is required, all procurement actions are reportable, not just the portion which exceeds $150,000. Reporting is not required if at the time of award, funds budgeted for procurements are less than or equal to $150,000 and are maintained below the threshold. The changes established in the Deviation have been effective since December 4, 2014, and are only being codified in this rule. We also added a provision to 40 CFR 33.502 to clarify that reports must be submitted by October 30th of each fiscal year, or 30 days after the end of the project period, whichever comes first. This revision is consistent with the reporting due date(s) established in the terms and conditions for assistance agreement recipients revised February 5, 2015. The change will incorporate terms that shortened the submission date from 90 days after the end of the project period to 30 days. The EPA previously incorporated these changes into existing agreements to ensure that final reports were received in a timely fashion to facilitate the close out process. The EPA cannot close out an assistance agreement until the final report is received. The changes codifies these terms and conditions for all assistance agreements for which reporting is required.

We made only minor revisions to 40 CFR 33.501. We revised 40 CFR 33.501(a) to change the term "grant" to "assistance agreement" to clarify that recipients of annual assistance agreements other than grants must maintain a bidder's list. We also removed the requirement for recipients to include the mailing address of any prime- or subcontractors in the bidder's list; a mailing address is no longer necessary because the information in the bidder's list is only handled electronically. Finally, revised 40 CFR 33.501(c) to change the phrase "a recipient under the CWSRF, DWSRF, or BCRLF Program" to "a recipient under the CWSRF, DWSRF, BCRLF, or other identified loan program" to clarify that the requirements are not limited to recipients of the programs currently listed in the rule; these changes are consistent with the changes to 40 CFR 33.303 and 40 CFR 33.411(b) discussed in sections IV.A and IV.D of this preamble, respectively.

Finally, we made one minor revision to 40 CFR 33.503 to clarify when reporting amounts of MBE and WBE participation as a percentage of total financial assistance agreement project procurement cost, recipients should only report funds used for procurements. This change is consistent with the existing requirements.

VII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act

The information collection activities in this rule will be submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 2536.01. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

Information requested as a result of the revisions relate to (1) the Contract Administration Forms which are required if there are DBE subcontractors involved in a procurement under 40 CFR 33.302 (d) and (e) (formerly 40 CFR 33.302(f) and (g)), (2) the EPA DBE Self Certification process, and (3) fair share objectives required of certain recipients of EPA financial assistance. The information that will be collected allows EPA to evaluate and ensure the effectiveness of, and compliance with, the program's requirements. Information gathered that may reasonably be regarded as proprietary or other confidential business information will be safeguarded from disclosure to unauthorized persons, consistent with applicable federal, state and local law. EPA has regulations concerning confidential business information. See 40 CFR part 2, subpart B.

Respondents/affected entities: Recipients of EPA financial assistance agreements and entities in the fields of construction, equipment, services and supplies who are intent on being prime contractors or subcontractors on EPA funded projects.

Respondent's obligation to respond: Contract Administration: Pursuant to 40 CFR 33.302, a recipient must require its prime contractor to have its DBE subcontractors complete EPA Form 6100–3—DBE Program Subcontractor Performance Form as part of the prime contractor's bid or proposal package. Furthermore, a recipient must require its prime contractor to complete and submit EPA Form 6100–4—DBE Program Subcontractor Utilization Form as part of the prime contractor's bid or proposal package.

Certification: Obtaining EPA DBE Certification is voluntary, however, in order to qualify and participate as an MBE or WBE prime or subcontractor for EPA recipients under EPA's DBE Program, an entity must be properly certified as detailed in 40 CFR 33.201.

Fair Share Negotiations: It is required that all financial assistance recipients, unless exempt under 40 CFR 33.411, negotiate objectives/goals for MBE/WBE utilization pursuant to 40 CFR 33.401.

Estimated number of respondents: 2,132.

Frequency of response: Contract Administration: Once during bid or proposal. *Certification:* Once during initial DBE certification and every three years as needed for re-certification. *Fair Share Negotiations:* Once Every Five Years.

Total estimated burden: 2,973 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $92,840 (per year), includes $0 annualized capital or operation & maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

This is rule being published as a direct final action. A public comment period prior to this publication was not required.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule. This action will improve the practical utility of the EPA's DBE program and minimize the burden to small entities. We have therefore concluded that this action will relieve regulatory burden for all directly regulated small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The costs involved in this action are imposed only by conditions of federal assistance. UMRA excludes from the definition[s] of "federal intergovernmental mandate" duties that arise from conditions of federal assistance. Additionally, this action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Because this rule conditions the use of federal assistance, it will not impose substantial direct compliance costs on State and local governments.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action has tribal implications. However, it will neither impose substantial direct compliance costs on federally recognized tribal governments, nor preempt tribal law. The amendments generally reduce the burden and compliance costs associated with 40 CFR part 33.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTA)

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations. The EPA made this determination because this rule does not affect the level of protection provided to human health or the environment.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 33

Environmental protection, Grant programs.

Dated: July 15, 2016.

Gina McCarthy,

Administrator.

For the reasons stated in the preamble, the Environmental Protection Agency is amending title 40, chapter I, of the Code of Federal Regulations as follows:

PART 33—PARTICIPATION BY DISADVANTAGED BUSINESS ENTERPRISES IN UNITED STATES ENVIRONMENTAL PROTECTION AGENCY PROGRAMS

■ 1. The authority citation for part 33 continues to read as follows:

Authority: 15 U.S.C. 637 note; 42 U.S.C. 4370d, 7601 note, 9605(f); E.O. 11625, 36 FR 19967, 3 CFR, 1971 Comp., p. 213; E.O. 12138, 49 FR 29637, 3 CFR, 1979 Comp., p. 393; E.O. 12432, 48 FR 32551, 3 CFR, 1983 Comp., p. 198, 2 CFR part 200.

Subpart A—General Provision

■ 2. Section 33.101 is amended by revising paragraph (a) to read as follows:

§ 33.101 What are the objectives of this part?

* * * * *

(a) To foster nondiscrimination in the award and administration of procurements under EPA financial assistance agreements. To that end, implementation of this rule with respect to grantees, sub-grantees, loan recipients, prime contractors, or subcontractors in particular States or locales—notably those where there is no apparent history of relevant discrimination—must comply with equal protection standards at that level, apart from the EPA disadvantaged business enterprise (DBE) Rule's constitutional compliance as a national matter;

* * * * *

■ 3. Section 33.102 is revised to read as follows:

§ 33.102 To whom does this part apply?

(a) If you are a recipient or prime contractor of any of the following types of funds, this part applies to you:

(1) An EPA financial assistance agreement.

(2) Grants or cooperative agreements used to capitalize revolving loan funds, including, but not limited to, the Clean Water State Revolving Loan Fund (CWSRF) Program under Title VI of the Clean Water Act, as amended, 33 U.S.C. 1381 *et seq.*, the Drinking Water State Revolving Fund (DWSRF) Program under section 1452 of the Safe Drinking Water Act, 42 U.S.C. 300j–12, and the Brownfields Cleanup Revolving Loan Fund (BCRLF) Program under section 104 of the Comprehensive Environmental Response, Compensation and Liability Act, 42 U.S.C. 9604.

(3) Special Appropriation Act Projects (SAAP) funding.

(4) A subaward from an EPA recipient to carry out the project or program under the Federal award.

(b) If you are letting a contract, and that contract is to be performed entirely outside the United States or its territories and insular possessions, this part does not apply to the contract.

(c) If you are letting a contract that is not being funded under an EPA financial assistance agreement or not being funded as part of the required match for an EPA financial assistance agreement, this part does not apply to the contract.

■ 4. Section 33.103 is amended by:

■ a. Revising the introductory text.

■ b. Adding definitions for "Contract," "Contractor," "Control," "Economically disadvantaged individual," "Expenditures," "Federal award," "Goods and services," "Ownership," "Procurement," "Relevant geographic market," "Socially disadvantaged individual," "Subaward," "Subcontract," "Subcontractor," "Subrecipient," and "Territories and Insular Possessions" in alphabetical order.

■ c. Revising the definitions of "Availability analysis," "Disadvantaged business enterprise (DBE)," "Disparity study," "Identified loan," "Recipient," "United States," and "Women's business enterprise."

■ d. Removing the definitions for "Construction," "Equipment," "Insular area," "Services," and "Supplies."

The revisions and additions read as follows:

§ 33.103 What do the terms in this part mean?

Terms not defined below shall have the meaning given to them in 2 CFR 200.1 as applicable. As used in this part:

Availability analysis means documentation of the availability of minority business enterprises (MBEs) and women's business enterprises (WBEs), that provide particular goods and services in a relevant geographic market, in relation to the total number of firms available in that area that provide the same goods or services.

* * * * *

Contract means a legal instrument by which a non-Federal entity purchases goods or services needed to carry out the project or program under a Federal award. The term as used in this part does not include a legal instrument, even if the non-Federal entity considers it a contract, when the substance of the transaction meets the definition of a Federal award or subaward (see *Subaward* as defined this section).

Contractor means an entity that receives a contract as defined in this section.

Control means both the strategic policy setting exercised by boards of directors and the day-to-day management and administration of business operations as described in 13 CFR 124.106.

* * * * *

Disadvantaged business enterprise (DBE) means an entity that is at least 51% owned or controlled by a socially and economically disadvantaged U.S citizen as described by Public Law 102–389 (42 U.S.C. 4370d) or an entity owned and controlled by a socially and economically disadvantaged individual as described by Title X of the Clean Air Act Amendments of 1990 (42 U.S.C. 7601 note); a Small Business Enterprise (SBE); a Small Business in a Rural Area (SBRA); or a Labor Surplus Area Firm (LSAF), a Historically Underutilized Business (HUB) Zone Small Business Concern, or a concern under a successor program.

Disparity study means an analysis of whether a disparity, or differences, exists between the number of MBEs and WBEs within the same industries in a relevant geographic market that are available to participate in EPA financial assistance agreements, and those that actually participate.

Economically disadvantaged individual means a socially disadvantaged individual whose ability to compete in the free enterprise system is impaired due to diminished capital and credit opportunities, as compared to others in the same business area who are not socially disadvantaged and as further defined by section 8(a)(6) of the Small Business Act (15 U.S.C. 637(a)(6)) and its implementing regulations (13 CFR 124.104). (See also 13 CFR 124.109 for special rules applicable to Indian tribes and Alaska Native Corporations; 13 CFR 124.110 for special rules applicable to Native Hawaiian Organizations). Under EPA's DBE Program, an individual claiming disadvantaged status must have an initial and continued personal net worth of less than or equal to the prevailing Department of Transportation (DOT) DBE Program economic disadvantaged threshold as described in 49 CFR part 26, subpart D.

Expenditures means charges made by a non-Federal entity to a project or program for which a Federal award was received. The charges may be reported on a cash or accrual basis, as long as the methodology is disclosed and is consistently applied.

(1) For reports prepared on a cash basis, expenditures are the sum of:

(i) Cash disbursements for direct charges for property and services;

(ii) The amount of indirect expense charged;

(iii) The value of third-party in-kind contributions applied; and

(iv) The amount of cash advance payments and payments made to subrecipients.

(2) For reports prepared on an accrual basis, expenditures are the sum of:

(i) Cash disbursements for direct charges for property and services;

(ii) The amount of indirect expense incurred;

(iii) The value of third-party in-kind contributions applied; and

(iv) The net increase or decrease in the amounts owed by the non-Federal entity for goods and other property received; services performed by employees, contractors, subrecipients, and other payees; and programs for which no current services or performance are required, such as annuities, insurance claims, or other benefit payments.

* * * * *

Federal award has either of the following meanings, as applicable:

(1) The Federal financial assistance that a non-Federal entity receives

directly from a Federal awarding agency or indirectly from a pass-through entity, as described in 2 CFR 200.101 Applicability; or the cost-reimbursement contract under the Federal Acquisition Regulations that a non-Federal entity receives directly from a Federal awarding agency or indirectly from a pass-through entity, as described in 2 CFR 200.101 (Applicability).

(2) The instrument setting forth the terms and conditions of a grant agreement, cooperative agreement, other agreement for assistance covered in paragraph (b) of 2 CFR 200.40 (Federal financial assistance), or the cost-reimbursement contract awarded under the Federal Acquisition Regulations.

(3) Federal award does not include other contracts that a Federal agency uses to buy goods or services from a contractor or a contract to operate Federal Government owned, contractor operated facilities (GOCOs).

* * * * *

Goods and services means tangible consumable items and tasks performed by individuals.

* * * * *

Identified loan means a loan project or set-aside activity receiving assistance from a recipient of an EPA financial assistance agreement to capitalize a revolving loan fund, that:

(1) In the case of the CWSRF Program, is a project funded from amounts equal to the capitalization grant;

(2) In the case of the DWSRF Program, is a loan project or set-aside activity funded from amounts up to the amount of the capitalization grant;

(3) In the case of the BCRLF Program, is a project that has been funded with EPA financial assistance; or

(4) In the case of other loan programs, is a project that has been funded with EPA financial assistance.

* * * * *

Ownership means at least 51 percent of an enterprise is unconditionally and directly owned by one or more socially and economically disadvantaged individuals who are citizens of the United States, except for concerns owned by Indian tribes, Alaska Native Corporations, Native Hawaiian Organizations, or Community Development Corporations (CDCs) as described in 13 CFR 124.105. See 13 CFR 124.3 for definition of unconditional ownership; and 13 CFR 124.109, 124.110, and 124.111, respectively, for special ownership requirements for concerns owned by Indian tribes, Alaska Native Corporations, Native Hawaiian Organizations, and Community Development Corporations.

Procurement means the acquisition of goods and services under a financial assistance agreement as defined by applicable regulations for the particular type of financial assistance received.

Recipient means a non-Federal entity that receives an EPA financial assistance agreement or is a sub-recipient of such agreement, including and not limited to loan recipients under the Clean Water State Revolving Fund Program, Drinking Water State Revolving Fund Program, and the Brownfields Cleanup Revolving Loan Fund Program.

Relevant geographic market means is the area of solicitation for a procurement as determined by the recipient which may include where the recipient has historically done business and/or plans to do business as it relates to new markets.

* * * * *

Socially disadvantaged individual means a person who has been subjected to racial or ethnic prejudice or cultural bias because of his or her identity as a member of a group without regard to his or her individual qualities and as further defined by the implementing regulations of section 8(a)(5) of the Small Business Act (15 U.S.C. 637(a)(5); 13 CFR 124.103; see also 13 CFR 124.109 for special rules applicable to Indian tribes and Alaska Native Corporations; 13 CFR 124.110 for special rules applicable to Native Hawaiian Organizations).

Subaward means an award provided by an EPA financial assistance agreement recipient to a subrecipient for the subrecipient to carry out part of an EPA award received by the recipient. It does not include payments to a contractor or payments to an individual that is a beneficiary of a Federal program. A subaward may be provided through any form of legal agreement, including an agreement that the pass-through entity considers a contract.

Subcontract means an agreement between an EPA financial assistance agreement's prime contractor and a subcontractor to provide goods and services.

Subcontractor means an entity engaged by an EPA financial assistance agreement's prime contractor to provide good and services.

Subrecipient means a non-Federal entity that receives a subaward from an EPA recipient to carry out part of an EPA program; but does not include an individual that is a beneficiary of such program.

Territories and Insular Possessions means any type of political division that is directly overseen by the United States as described in U.S. Code: Title 48.

United States means any of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico and any other territories and possessions of the United States.

Women's business enterprise (WBE) means a business concern which is at least 51% owned or controlled by women for purposes of EPA's 8% statute or a business concern which is at least 51% owned and controlled by women for purposes for EPA's 10% statute. Determination of ownership by a married woman in a community property jurisdiction will not be affected by her husband's 50 percent interest in her share. Similarly, a business concern that is more than 50 percent owned by a married man will not become a qualified WBE by virtue of his wife's 50 percent interest in his share.

■ 5. Section 33.104 is amended by:

■ a. Revising paragraphs (a), (c) introductory text, and (c)(2) and (3).

■ b. Adding paragraph (c)(4).

■ c. Removing paragraph (d).

The revisions and addition read as follows:

§ 33.104 May recipients apply for a waiver from the requirements of this part?

(a) A recipient may apply for a waiver from any of the requirements of this part that are not specifically based on a statute or Executive Order, by submitting a written request to the Director of the Office of Small Business Programs (OSBP).

* * * * *

(c) The OSBP Director has the authority to approve a recipient's request. If the OSBP Director grants a recipient's request, the recipient may administer its program as provided in the request, subject to the following conditions:

* * * * *

(2) There is a five year limitation on the duration of the recipient's modified program. Should it be necessary to extend a waiver beyond the five year period, recipients are required to submit a new waiver request at least 60 days prior to the modified program's expiration date. Should the recipient fail to submit a new waiver request prior to the modified program's expiration date, the recipient will be required to comply with the provisions of this part and all terms agreed upon as a condition of the waiver will expire; and

(3) Any other conditions the OSBP Director makes on the grant of the waiver.

(4) The OSBP Director may end a program waiver at any time upon notice

to the recipient and require a recipient to comply with the provisions of this part.

■ 6. Section 33.105 is revised to read as follows:

§ 33.105 What are the compliance and enforcement provisions of this part?

If a recipient fails to comply with any of the requirements of this part, EPA may take remedial action under 2 CFR 200.338, as appropriate, or any other action authorized by law, including, but not limited to, enforcement under 18 U.S.C. 1001 and/or the Program Fraud Civil Remedies Act of 1986 (31 U.S.C. 3801 *et seq.*). Examples of the remedial actions include, but are not limited to:

(a) Temporarily withholding cash payments pending correction of the deficiency by the recipient or more severe enforcement action by EPA;

(b) Disallowing (that is, denying both use of funds and any applicable matching credit for) all or part of the cost of the activity or action not in compliance;

(c) Wholly or partly suspending or terminating the EPA award;

(d) Initiating suspension or debarment proceedings as authorized under 2 CFR part 180 and EPA regulations (or in the case of a pass-through entity, recommend such a proceeding be initiated by EPA);

(e) Withholding further awards for the project or program; and

(f) Taking other remedies that may be legally available.

■ 7. Section 33.107 is amended by:

■ a. Redesignating paragraphs (b) and (c) as paragraphs (c) and (d), respectively.

■ b. Adding new paragraph (b).

The addition reads as follows:

§ 33.107 What are the rules governing availability of records, cooperation, and intimidation and retaliation?

* * * * *

(b) *Retention requirements and access for records.* Recipients are required to adhere to the requirements set forth in 2 CFR 200.333 through 200.337 for record retention and access to records requirements.

* * * * *

■ 8. Appendix A is added to subpart A of part 33 to read as follows:

Appendix A to Subpart A of Part 33—Term and Condition

Each procurement contract signed by an EPA financial assistance agreement recipient or subrecipient, including those for an identified loan under an EPA financial assistance agreement capitalizing a revolving loan fund, must include provisions under 2 CFR part 200, appendix II, as applicable, as well as the following term and condition:

The contractor shall not discriminate on the basis of race, color, national origin or sex in the performance of this contract. The contractor shall carry out applicable requirements of 40 CFR part 33 in the award and administration of contracts awarded under EPA financial assistance agreements. Failure by the contractor to carry out these requirements is a material breach of this contract, which may result in the termination of this contract or other legally available remedies.

Subpart B—Certification

■ 9. Section 33.202 is revised to read as follows:

§ 33.202 How does an entity qualify as an MBE or WBE under EPA's 8% statute?

To qualify as an MBE or WBE under EPA's 8% statute, an entity must establish that it is owned or controlled by socially and economically disadvantaged individuals who are of good character and citizens of the United States. An entity need not demonstrate potential for success.

■ 10. Section 33.203 is revised to read as follows:

§ 33.203 How does an entity qualify as an MBE or WBE under EPA's 10% statute?

(a) *Qualifications.* To qualify as an MBE or WBE under EPA's 10% statute, an entity must establish that it is owned and controlled by socially and economically disadvantaged individuals who are of good character and citizens of the United States.

(b) *Presumptions.* In accordance with Title X of the Clean Air Act Amendments of 1990, 42 U.S.C. 7601 note, Black Americans, Hispanic Americans, Native Americans, Asian Americans, Women and Disabled Americans are presumed to be socially and economically disadvantaged individuals. In addition, the following institutions are presumed to be entities owned and controlled by socially and economically disadvantaged individuals: HBCUs, Minority Institutions (including Tribal Colleges and Universities and Hispanic-Serving Institutions) and private and voluntary organizations controlled by individuals who are socially and economically disadvantaged.

(c) *Individuals not members of designated groups.* Nothing in this section shall prohibit any member of a racial or ethnic group that is not designated as socially and economically disadvantaged under paragraph (b) of this section from establishing that they have been impeded in developing a business concern as a result of racial or ethnic discrimination.

(d) *Rebuttal of presumptions.* The presumptions established by paragraph (b) of this section may be rebutted with respect to a particular entity if it is reasonably established that the individual at issue is not experiencing impediments as a result of the individual's identification as a member of a specified group.

(e) *Joint ventures.* A joint venture may be considered owned and controlled by socially and economically disadvantaged individuals, notwithstanding the size of such joint venture, if a party to the joint venture is an entity that is owned and controlled by a socially and economically disadvantaged individual, and that entity owns 51% of the joint venture. As a party to a joint venture, a person who is not an economically disadvantaged individual, or an entity that is not owned and controlled by a socially and economically disadvantaged individual, may not be a party to more than two awarded contracts in a fiscal year solely by joint venture with a socially and economically disadvantaged individual or entity.

■ 11. Section 33.204 is revised to read as follows:

§ 33.204 What certifications are acceptable for establishing MBE or WBE status under the EPA DBE Program?

(a) EPA accepts the following certifications as being acceptable for establishing MBE or WBE status under the EPA DBE Program:

(1) The United States Small Business Administration (SBA), under its 8(a) Business Development Program (13 CFR part 124, subpart A), Small Disadvantaged Business (SDB) Program (13 CFR part 124, subpart B), or Economically Disadvantaged Woman Owned Small Business (EDWOSB) Program (13 CFR part 127, subpart B);

(2) The United States Department of Transportation (DOT), under its regulations for Participation by Disadvantaged Business Enterprises in DOT Programs (49 CFR parts 23 and 26) with U.S. citizenship;

(3) Any Indian Tribal Government, State Government, local Government or independent private organization certification that meets the criteria set forth in § 33.202 or § 33.203; or

(4) The EPA DBE self-certification as described in § 33.205.

(b) Such certifications shall be considered acceptable for establishing MBE or WBE status, as appropriate, under EPA's DBE Program as long as the certification meets EPA's U.S. citizenship requirement under § 33.202 or § 33.203.

■ 12. Section 33.205 is revised to read as follows:

§ 33.205 How does an entity become self-certified by EPA?

(a) An entity may self-certify as an MBE or WBE under the EPA DBE Program. To self-certify, the entity must register in the EPA Small Business Vendor Profile System (SBVPS) and attest to meeting the eligibility requirements set forth in § 33.202 or § 33.203.

(b) EPA DBE Program's self-certifications are only applicable to opportunities funded by EPA financial assistance agreements and are not recognized by other federal, state or local organizations.

■ 13. Section 33.206 is revised to read as follows:

§ 33.206 Is there a list of EPA certified MBEs and WBEs?

A list of firms that have chosen to self-certify as an MBE or WBE under the EPA DBE Program can be accessed through the EPA SBVPS on the OSBP Web site. EPA will not maintain a list of firms certified through other entities.

§ 33.207 [Removed and Reserved]

■ 14. Section 33.207 is removed and reserved.

■ 15. Section 33.208 is revised to read as follows:

§ 33.208 How long does an MBE or WBE self-certification from EPA last?

Self-certifications are valid for a period of three years from the date an entity is self-certified in the EPA SBVPS. Entities are required to re-enter their registration information in the EPA SBVPS every three years in order to maintain MBE or WBE status under the DBE program. Entries in the EPA SBVPS older than three years will be automatically removed from the system.

§ 33.209 [Removed and Reserved]

■ 16. Section 33.209 is removed and reserved.

■ 17. Section 33.210 is revised to read as follows:

§ 33.210 Does an entity self-certified as an MBE or WBE by EPA need to keep EPA informed of any changes that may affect the entity's certification?

Should there be any changes to the entity's circumstances that affects its ability to meet disadvantaged status, ownership, and/or control requirements of this subpart, the entity must remove its self-certification entry in the EPA SBVPS within 30 days of the occurrence of the change. Failure to comply may result in the loss of MBE or WBE certification under EPA's DBE Program and EPA may take other remedies that may be legally available. Failure to comply may result in the loss of MBE or WBE certification under EPA's DBE Program, and EPA may take other remedies that may be legally available.

§ 33.211 [Removed and Reserved]

■ 18. Section 33.211 is removed and reserved.

Subpart C—Good Faith Efforts

■ 19. Section 33.301 is revised to read as follows:

§ 33.301 What does this subpart require?

(a) The good faith efforts are methods used by all EPA recipients to ensure that DBEs have the opportunity to compete for procurements funded by EPA financial assistance dollars.

(b) A recipient, including one exempted from applying the fair share objective requirements by § 33.411, is required to make good faith efforts whenever making procurements under an EPA financial assistance agreement.

(c) Good faith efforts are required even if the fair share objectives have been achieved under subpart D.

(d) Methods used to adhere to good faith requirements must be documented and retained in the recipient's records; this documentation should include, but is not limited to, email logs, phone logs, electronic searches and communication, handouts, flyers or similar records.

(e) Recipients are required to ensure that the requirements of this subpart are passed down to all sub-recipients/prime contractors.

(f) There are no exemptions to the requirements of this subpart.

(g) This subpart does not negate the post federal award requirements set forth in 2 CFR part 200.

(h) The following is a list of actions a recipient must perform to satisfy the good faith effort requirement:

(1) Ensure DBEs are made aware of contracting opportunities to the fullest extent practicable through outreach and recruitment activities by placing DBEs on solicitation lists and soliciting them whenever they are potential sources.

(2) Make information on forthcoming opportunities available to DBEs and arrange time frames for contracts and establish delivery schedules, where the requirements permit, in a way that encourages and facilitates participation by DBEs in the competitive process. This includes, whenever possible, posting solicitations for bids or proposals for a minimum of 30 calendar days before the bid or proposal closing date.

(3) Consider in the contracting process whether firms competing for large contracts could subcontract with DBEs; this includes, where appropriate, breaking out requirements into economically feasible units to facilitate DBE participation.

(4) Encourage contracting with a consortium of DBEs when a contract is too large for one of these firms to handle individually.

(5) Effectively using the services of available minority/women community organizations; minority/women contractors' groups; local, state, and Federal minority/women business assistance offices; and other organizations, when feasible, to conduct the efforts described in paragraphs (h)(1) through (4) of this section.

(i) A recipient should make every attempt to conduct the efforts described in paragraphs (h)(1) through (5) of this section. In the event that one or more of the aforementioned efforts cannot be performed, the circumstances that have prohibited the full execution of each step should be documented and retained in the recipient's records. Recipients that fail to meet their fair share goals will not be penalized provided they attempt to follow the good faith efforts and adequately document the methods used to solicit DBEs. However, failure to retain proper documentation may constitute noncompliance and result in remedial action as described in § 33.105.

■ 20. Section 33.302 is amended by revising paragraphs (c) through (i) to read as follows:

§ 33.302 Are there any additional contract administration requirements?

* * * * *

(c) If a DBE subcontractor fails to complete work under the subcontract for any reason, the recipient must require the prime contractor to employ the good faith efforts described in § 33.301(h) if soliciting a replacement subcontractor.

(d) A recipient must require its prime contractor to have its DBE subcontractors complete EPA Form 6100–3—DBE Program Subcontractor Performance Form. A recipient must then require its prime contractor to include all completed forms as part of the prime contractor's bid or proposal package.

(e) A recipient must require its prime contractor to complete and submit EPA Form 6100–4—DBE Program Subcontractor Utilization Form as part of the prime contractor's bid or proposal package.

(f) Copies of EPA Form 6100–2—DBE Program Subcontractor Participation Form, EPA Form 6100–3—DBE Program Subcontractor Performance Form, and EPA Form 6100–4—DBE Program

Subcontractor Utilization Form may be obtained online from EPA OSBP's Home Page.

(g) Failure to include EPA Form 6100–3 and EPA Form 6100–4 in a bid or proposal package may constitute non-responsiveness. A recipient may consider this non-responsiveness in evaluating a prime contractor's proposal.

(h) A recipient must ensure that each procurement contract it awards contains the term and condition specified in 2 CFR part 200, appendix II, concerning compliance with the requirements of this part. A recipient must also ensure that this term and condition is included in each procurement contract awarded by an entity receiving an identified loan under a financial assistance agreement to capitalize a revolving loan fund.

(i) In addition to requirements stated above, all procurement contracts awarded by a recipient must contain provisions detailed in 2 CFR part 200, appendix II, as applicable.

■ 21. Section 33.303 is revised to read as follows:

§ 33.303 Are there special rules for loans under EPA financial assistance agreements?

A recipient of an EPA financial assistance agreement to capitalize a revolving loan fund, including, but not limited to, a State under the CWSRF or DWSRF or an eligible entity under the Brownfields Cleanup Revolving Loan Fund program, must require that borrowers receiving identified loans comply with the good faith efforts described in § 33.301 and the contract administration requirements of § 33.302. This provision does not require that such private and nonprofit borrowers expend identified loan funds in compliance with any other procurement procedures contained in 2 CFR part 200, subpart D (Post Federal Award Requirements, Procurement Standards), or 40 CFR part 35, subpart O, as applicable.

■ 22. Section 33.304 is amended by revising the section heading and paragraphs (a) through (c) to read as follows:

§ 33.304 What special rules apply to a Native American (either as an individual, organization, Tribe or Tribal Government or consortium) recipient or prime contractor when following the good faith efforts?

(a) A Native American (either as an individual, organization, corporation, Tribe or Tribal Government or consortium) recipient or prime contractor must follow the good faith efforts in § 33.301(h) only if doing so would not conflict with existing Tribal or Federal law, including but not limited to the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450e), which establishes, among other things, that any federal contract, subcontract, grant, or subgrant awarded to Indian organizations or for the benefit of Indians, shall require preference in the award of subcontracts and subgrants to Indian organizations and to Indian-owned economic enterprises.

(b) Tribal organizations awarded an EPA financial assistance agreement have the ability to solicit and recruit Indian organizations and Indian-owned economic enterprises and give them preference in the award process prior to undertaking the good faith efforts. Tribal governments with promulgated tribal laws and regulations concerning the solicitation and recruitment of Native-owned and other minority business enterprises, including women-owned business enterprises, have the discretion to utilize these tribal laws and regulations in lieu of the good faith efforts. If the effort to recruit Indian organizations and Indian-owned economic enterprises is not successful, then the recipient must follow the good faith efforts. All tribal recipients still must retain records documenting compliance in accordance with § 33.501 and must report to EPA on their accomplishments in accordance with § 33.502.

(c) Any recipient, whether or not Native American, of an EPA financial assistance agreement for the benefit of Native Americans, is required to solicit and recruit Indian organizations and Indian-owned economic enterprises and give them preference in the award process prior to undertaking the good faith efforts. If the efforts to solicit and recruit Indian organizations and Indian-owned economic enterprises is not successful, then the recipient must follow the good faith efforts.

* * * * *

Subpart D—Fair Share Objectives

■ 23. Section 33.401 is revised to read as follows:

§ 33.401 What does this subpart require?

A recipient must either negotiate with the appropriate EPA award official or his/her designee fair share objectives for MBE and WBE participation in procurement under the financial assistance agreements, or use the approved fair share objective of another recipient with the same or similar relevant geographic buying market, purchasing the same or similar items.

■ 24. Section 33.402 is revised to read as follows:

§ 33.402 Are there special rules for loans under EPA financial assistance agreements?

(a) A recipient of an EPA financial assistance agreement to capitalize revolving loan funds must either:

(1) Apply its own fair share objectives negotiated with EPA under § 33.401 to identified loans using a substantially similar relevant geographic market;

(2) Negotiate separate fair share objectives with entities receiving identified loans, as long as such separate objectives are based on demonstrable evidence of availability of MBEs and WBEs in accordance with this subpart; or

(3) Use the approved fair share objective of another recipient with the same or similar relevant geographic buying market, with the same or similar items.

(b) If procurements will occur over more than one year, the recipient should apply the fair share objectives to the year in which the procurement action occurs.

■ 25. Section 33.403 is revised to read as follows:

§ 33.403 What is a fair share objective?

A fair share objective is an objective based on the capacity and availability of qualified, certified MBEs and WBEs in the relevant geographic market compared to the number of all qualified entities in the same market, to reflect the level of MBE and WBE participation expected absent the effects of discrimination. A fair share objective is not a quota.

■ 26. Section 33.404 is revised to read as follows:

§ 33.404 When must a recipient negotiate fair share objectives with EPA?

A recipient must submit its proposed MBE and WBE fair share objectives and supporting documentation to EPA within 90 days after its acceptance of its financial assistance award. EPA must respond in writing to the recipient's submission within 45 days of receipt, either agreeing with the submission or providing initial comments for further negotiation. Failure to respond within this time frame may be considered as agreement by EPA with the fair share objectives submitted by the recipient. MBE and WBE fair share objectives must be agreed upon by the recipient and EPA before funds may be expended for procurement under the recipient's financial assistance agreement.

■ 27. Section 33.405 is amended by:

■ a. Revising paragraphs (a), (b) introductory text, and (b)(1) and (2);

■ b. Adding paragraph (c)(4).

The revisions and addition read as follows:

§ 33.405 How does a recipient determine its fair share objectives?

(a) Unless a recipient chooses to use the approved fair share objective of another recipient, it must determine its fair share objectives based on demonstrable evidence of the number of certified MBEs and WBEs that are ready, willing, and able to perform in the relevant geographic market. The market may be a geographic region of a State, an entire State, or a multi-State area. Fair share objectives must reflect the recipient's determination of the level of MBE and WBE participation it would expect absent the effects of discrimination. A recipient must propose separate objectives for MBEs and WBEs.

(b) *Step 1.* A recipient must first determine a base figure for the relative availability of MBEs and WBEs. The following are examples of approaches that a recipient may take. Any percentage figure derived from one of these examples should be considered a basis from which a recipient begins when examining evidence available in its jurisdiction. These examples are provided as a starting point and are not intended as an exhaustive list.

(1) *MBE and WBE directories and Census Bureau data.* Separately determine the number of certified MBEs and WBEs that are ready, willing, and able to perform in the relevant geographic market from an MBE/WBE directory such as those provided by the Department of Transportation. When using the Census Bureau's County Business Pattern (CBP) database, determine the number of all qualified businesses available in the market that perform work in the same business industries. Separately divide the number of MBEs and WBEs by the number of all businesses to derive a base figure for the relative availability of MBEs and WBEs in the market.

(2) *Data from a disparity study.* Use a percentage figure derived from data in a valid, applicable disparity study conducted within the preceding ten years comparing the available MBEs and WBEs in the relevant geographic market with their actual usage by entities for procurements in the same business industries.

* * * * *

(c) * * *

(4) Unless exempt under § 33.411, a recipient that fails to establish and implement goals as provided in this section will be considered noncompliant and EPA may take remedial action under 2 CFR 200.338, as appropriate, or any other action authorized by law, including, but not limited to, enforcement under 18 U.S.C. 1001 and/or the Program Fraud Civil Remedies Act of 1986 (31 U.S.C. 3801 *et seq.*).

■ 28. Section 33.407 is revised to read as follows:

§ 33.407 How long do MBE and WBE fair share objectives remain in effect?

Once MBE and WBE fair share objectives have been negotiated, they will remain in effect for five fiscal years unless there are significant changes to the data supporting the fair share objectives. The fact that a disparity study utilized in negotiating fair share objectives has become more than ten years old during the five-year period does not by itself constitute a significant change requiring renegotiation.

■ 29. Section 33.408 is amended by revising paragraph (a) to read as follows:

§ 33.408 May a recipient use race and/or gender conscious measures as part of this program?

(a) Should the good faith efforts described in subpart C of this part or other race and/or gender neutral measures prove to be inadequate to achieve an established fair share objective, race and/or gender conscious action (*e.g.*, apply the subcontracting suggestion in § 33.301(h)(3) to MBEs and WBEs) is available to a recipient and its prime contractor to more closely achieve the fair share objectives, subject to § 33.409. Under no circumstances are race and/or gender conscious actions required by EPA.

* * * * *

■ 30. Section 33.410 is revised to read as follows:

§ 33.410 Can a recipient be penalized for failing to meet its fair share objectives?

A recipient cannot be penalized, or treated by EPA as being in noncompliance with this subpart, solely because its MBE or WBE participation does not meet its applicable fair share objective. However, EPA may take remedial action under 2 CFR 200.338, as appropriate, or any other action authorized by law, including, but not limited to, enforcement under 18 U.S.C. 1001 and/or the Program Fraud Civil Remedies Act of 1986 (31 U.S.C. 3801 *et seq.*) for failure to comply with the provisions of this subpart.

■ 31. Section 33.411 is amended by revising paragraphs (a) through (c) to read as follows:

§ 33.411 Who may be exempted from this subpart?

(a) *General.* A recipient of an EPA financial assistance agreement in the amount of $1 million or less for any single assistance agreement, or of more than one financial assistance agreement with a combined total of $1 million or less in any one fiscal year, is not required to apply the fair share objective requirements of this subpart. This exemption is limited to the fair share objective requirements of this subpart.

(b) *Clean Water State Revolving Fund (CWSRF) Program, Drinking Water State Revolving Fund (DWSRF) Program, Brownfields Cleanup Revolving Loan Fund (BCRLF) Program or other identified loan recipients.* A recipient under the CWSRF, DWSRF, BCRLF, or other identified loan program is not required to apply the fair share objective requirements of this subpart to an entity receiving one or more identified loans in an amount of $1 million or less in any one fiscal year. This exemption is limited to the fair share objective requirements of this subpart.

(c) *U.S. Territory and Insular Possession, and Tribal and Intertribal Consortia recipients of program assistance agreements that can be included in Performance Partnership Grants (PPGs) under 40 CFR part 35, subparts A and B, respectively.* U.S Territory and Insular Possession, and Tribal and Intertribal Consortia recipients of PPG eligible grants are not required to apply the fair share objective requirements of this subpart to those grants. This exemption is limited to the fair share objective requirements of this subpart.

* * * * *

§ 33.412 [Removed and Reserved]

■ 32. Section 33.412 is removed and reserved.

Subpart E—Recordkeeping and Reporting

■ 33. Section 33.501 is amended by revising paragraphs (b) introductory text, (b)(2), and (c) to read as follows:

§ 33.501 What are the recordkeeping requirements of this part?

* * * * *

(b) A recipient of a Continuing Environmental Program Grant or other annual assistance agreements must create and maintain a bidders list. In addition, a recipient of an EPA financial assistance agreement to capitalize a revolving loan fund also must require entities receiving identified loans to create and maintain a bidders list if the recipient of the loan is subject to, or chooses to follow, competitive bidding requirements (See *e.g.*, § 33.303). The purpose of a bidders list is to provide the recipient and entities receiving identified loans who conduct competitive bidding with as accurate a database as possible about the universe of MBE/WBE and non-MBE/WBE prime and subcontractors. The list must include all firms that bid or quote on prime contracts, or bid or quote subcontracts on EPA assisted projects, including both MBE/WBEs and non-MBE/WBEs. The bidders list must only be kept until the assistance agreement project period has expired and the recipient is no longer receiving EPA funding under the assistance agreement. For entities receiving identified loans, the bidders list must only be kept until the project period for the identified loan has ended. The following information must be obtained from all prime and subcontractors:

* * * * *

(2) Entity's telephone number and email address;

* * * * *

(c) *Exemptions.* A recipient of an EPA financial assistance agreement in the amount of $250,000 or less for any single assistance agreement, or of more than one financial assistance agreement with a combined total of $250,000 or less in any one fiscal year, is exempt from the paragraph (b) of this section requirement to create and maintain a bidders list. Also, a recipient under the CWSRF, DWSRF, BCRLF, or other identified loan program, is not required to apply the paragraph (b) of this section bidders list requirement of this subpart to an entity receiving an identified loan in an amount of $250,000 or less, or to an entity receiving more than one identified loan with a combined total of $250,000 or less in any one fiscal year. This exemption is limited to the paragraph (b) of this section bidders list requirements of this subpart.

■ 34. Section 33.502 is revised to read as follows:

§ 33.502 What are the reporting requirements of this part?

(a) Recipients are required to report MBE and WBE participation annually on EPA Form 5700–52A when one or more of the following conditions are met.

(1) There are funds budgeted for procurements, including funds budgeted for direct procurement by the recipient or procurement under sub-awards or loans in the "Other" procurement category that exceed the simplified acquisition threshold amount of $150,000;

(2) If at the time of award the budgeted funds for procurement exceed $150,000, but actual expenditures fall below; or

(3) If subsequent amendments and funding cause the total amount of procurement to surpass the $150,000 threshold.

(b) Those recipients exempted under § 33.411 from the requirement to apply the fair share objectives are required to report if one or more of the conditions stated above is met.

(c) Recipients of financial assistance agreements that capitalize revolving loan programs must require entities receiving identified loans to submit their MBE and WBE participation reports on an annual basis, if one or more of the conditions stated above is met. Reports should be submitted to the financial assistance agreement recipient, rather than to EPA.

(d) Where reporting is required, all procurement actions are reportable, not just that portion that exceeds $150,000.

(e) Reporting is not required if at the time of award, funds budgeted for procurements are less than or equal to $150,000 and are maintained below the threshold.

(f) Reports are due by October 30th of each fiscal year, or 30 days after the end of the project period, whichever comes first.

■ 35. Section 33.503 is amended by revising paragraph (a) to read as follows:

§ 33.503 How does a recipient calculate MBE and WBE participation for reporting purposes?

(a) *General.* Only certified MBEs and WBEs are to be counted towards MBE/WBE participation. Amounts of MBE and WBE participation are calculated as a percentage of total financial assistance agreement project procurement costs, which include the match portion of the project costs, if any. Recipients should only report funds used for procurements. For recipients of financial assistance agreements that capitalize revolving loan programs, the total amount is the total procurement dollars in the amount of identified loans equal to the capitalization amount.

* * * * *

Appendix A to Part 33 [Removed]

■ 36. Appendix A to part 33 is removed.

[FR Doc. 2016–17510 Filed 7–27–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Parts 360, 365, 366, 368, 385, 387, 390 and 392

[Docket No. FMCSA–1997–2349]

RIN 2126–AB85; Formerly 2126–AA22

Unified Registration System; Correction

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Final rule; correction.

SUMMARY: FMCSA is correcting the effective and compliance dates for its August 23, 2013, Unified Registration System (URS) final rule, as revised on October 21, 2015. The 2013 URS final rule was issued to improve the registration process for motor carriers, property brokers, freight forwarders, Intermodal Equipment Providers (IEPs), hazardous materials safety permit (HMSP) applicants, and cargo tank facilities required to register with FMCSA, and streamline the existing Federal registration processes to ensure the Agency can more efficiently track these entities. The October 21, 2015 final rule made slight revisions to the 2013 rule and delayed the effective dates of that rule. This final rule corrects the effective and compliance dates, revised in 2015, and corrects regulatory provisions that have not yet gone into effect, as well as several temporary sections that are in effect already, to allow FMCSA additional time to complete the information technology (IT) systems work.

DATES: *Effective Dates:* The effective of this rule is July 28, 2016.

The effective date of the rule published at 80 FR 63695 (October 21, 2015), is delayed until January 14, 2017, and §§ 365.T106, 368.T3, and 390.T200 are effective until January 13, 2017.

The corrections to the rule published October 21, 2015 (80 FR 63695), are effective on January 14, 2017.

The effective date of the rule published at 78 FR 52608 (August 23, 2013) is further delayed until January 14, 2017.

Compliance Dates: The compliance date for the rule published at 80 FR 63695 (October 21, 2015), is delayed until January 14, 2017, and new applicants must comply with §§ 365.T106, 368.T3 or 390.T200 (as applicable) until January 13, 2017; private hazardous material carriers and exempt for-hire carriers must comply with § 387.19 or § 387.43 (as applicable) by April 14, 2017; and all entities must comply with § 366.2 by April 14, 2017.

ADDRESSES: All background documents, comments, and materials related to this rule may be viewed in docket number FMCSA–1997–2349 using either of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.*
- Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

FOR FURTHER INFORMATION CONTACT: Mr. Kenneth Riddle, 1200 New Jersey Avenue SE., Washington, DC 20590–0001, by telephone at (202) 366–9616 or via email at *kenneth.riddle@dot.gov.* Office hours are from 8:00 a.m. to 4:30 p.m. ET, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Public Participation

Viewing Documents

To view comments submitted to previous rulemaking documents on this subject, go to *http://www.regulations.gov* and click on the "Read Comments" box in the upper right hand side of the screen. Then, in the "Keyword" box, insert "FMCSA–1997–2349" and click "Search." Next, click "Open Docket Folder" in the "Actions" column. Finally, in the "Title" column, click on the document you would like to review. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays.

Privacy Act

All comments received were posted without change to *http://www.regulations.gov.* In accordance with 5 U.S.C. 553(c), DOT previously solicited comments from the public to better inform its rulemaking process. DOT posted these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

Corrections

The FMCSA is correcting the effective and compliance dates for its August 23, 2013, Unified Registration System (URS) final rule, as revised on October 21, 2015, in order to delay implementation of the URS provisions. While the FMCSA had hoped to be able to reach full implementation by September 30, 2016, unforeseen delays and complications in the IT development process require that we push the full implementation back until January 14, 2017. These delays include added complexities due to an unrelated system migration to the cloud and also due to the logistics of transferring millions of records.

In order to make this change, FMCSA must correct regulatory provisions that have not yet gone into effect, as well as several temporary sections that are in effect already. The method for making corrections differs depending upon whether or not the provision being corrected has gone into effect. First, under the heading "**Federal Register** corrections," we provide the corrections for those provisions that are not yet in effect; these corrections will update the effective date for those provisions from September 30, 2016, to January 14, 2017. This will also update the compliance dates for certain provisions from December 31, 2016, to April 14, 2017.

We are also making minor corrections to fix errors found in the final rule published on October 21, 2015. In § 366.4, we are adding a sentence to clarify the requirements for motor carriers operating in Hawaii or Alaska, as these were inadvertently not covered in the original text. In § 385.305, we are correcting the reference to the online registration form MCSA–1, which was published without the "1" after the hyphen. In § 387.301, we are correcting the text in paragraph (a)(1) to clarify the financial responsibility requirements for school buses, including third parties providing school bus services. We have identified this as an area causing confusion, so a correction is needed.

After those corrections, numbered 1 through 6, we present the corrections to those provisions that came into effect on December 12, 2015. These corrections, which follow the "CFR amendments" heading, are presented as you would see amendatory instructions in any final rule. The result of these corrections will be to extend the effective dates of the temporary provisions in parts 365, 368, and 390 to January 14, 2017.

Federal Register Corrections

In FR Doc. 2015–26625 appearing on page 63695 in the **Federal Register** of Wednesday, October 21, 2015 (80 FR 63695), make the following corrections:

1. Beginning on page 63702, in the first column, in amendatory instruction #1 and continuing through all of the amendatory instructions except for #5, #24, and #59, the date "September 30, 2016" is corrected to read "January 14, 2017".

2. On page 63706, in the first column, in § 366.2, the date "December 31, 2016" is corrected to read "April 14, 2017".

3. On page 63706, in the first column, in § 366.4(a), the text is corrected to read "Every motor carrier, except a motor carrier operating exclusively in Alaska or Hawaii, must designate process agents for all 48 contiguous States and the District of Columbia, unless its operating authority registration is limited to fewer than 48 States and DC. When a motor carrier's operating authority registration is limited to fewer than 48 States and DC, it must designate process agents for each State in which it is authorized to operate and for each State traversed during such operations. Every motor carrier operating in the United States in the course of transportation between points in a foreign country shall file a designation for each State traversed. Every motor carrier maintaining a principal place of business and operating exclusively in Alaska or Hawaii must designate a process agent for the State where operations are conducted."

4. On page 63707, in the second column, in § 385.305(b)(2), the phrase "Form MCSA–," is corrected to read "Form MCSA–1,".

5. On page 63709, in the first column, in § 387.19, the date "December 31, 2016" is corrected to read "April 14, 2017".

6. On page 63709, in the third column, in § 387.301(a)(1), the text is corrected by adding the following sentence at the end of the paragraph: "Passenger motor carriers exempt under § 387.27 of this part are not subject to this limitation on transportation or required to file evidence of financial responsibility."

CFR Amendments

List of Subjects

49 CFR Part 360

Administrative practice and procedure, Brokers, Buses, Freight forwarders, Hazardous materials transportation, Highway safety, Insurance, Motor carriers, Motor vehicle safety, Moving of household goods, Penalties, Reporting and recordkeeping requirements, Surety bonds.

49 CFR Part 365

Administrative practice and procedure, Brokers, Buses, Freight forwarders, Motor carriers, Moving of household goods.

49 CFR Part 366

Brokers, Motor carriers, Freight forwarders, Process agents.

49 CFR Part 368

Administrative practice and procedure, Insurance, Motor carriers.

49 CFR Part 385

Administrative practice and procedure, Highway safety, Incorporation by reference, Mexico, Motor carriers, Motor vehicle safety, Reporting and recordkeeping requirements.

49 CFR Part 387

Buses, Freight, Freight forwarders, Hazardous materials transportation, Highway safety, Insurance, Intergovernmental relations, Motor carriers, Motor vehicle safety, Moving of household goods, Penalties, Reporting and recordkeeping requirements, Surety bonds.

49 CFR Part 390

Highway safety, Intermodal transportation, Motor carriers, Motor vehicle safety, Reporting and recordkeeping requirements.

49 CFR Part 392

Alcohol abuse, Drug abuse, Highway safety, Motor carriers.

In consideration of the foregoing, FMCSA is amending 49 CFR chapter III, subchapter B, parts 365, 368, and 390 are corrected by making the following correcting amendments:

PART 365—RULES GOVERNING APPLICATIONS FOR OPERATING AUTHORITY

■ 1. The authority citation for part 365 continues to read as follows:

Authority: 5 U.S.C. 553 and 559; 49 U.S.C. 13101, 13301, 13901–13906, 14708, 31138, and 31144; 49 CFR 1.87.

■ 2. Revise § 365.T106(d) to read as follows:

§ 365.T106 Starting the application process: URS online application.

* * * * *

(d) This section is in effect from December 12, 2015 through January 13, 2017.

PART 368—APPLICATION FOR A CERTIFICATE OF REGISTRATION TO OPERATE IN MUNICIPALITIES IN THE UNITED STATES ON THE UNITED STATES-MEXICO INTERNATIONAL BORDER OR WITHIN THE COMMERCIAL ZONES OF SUCH MUNICIPALITIES

■ 3. The authority citation for part 368 continues to read as follows:

Authority: 49 U.S.C. 13301 and 13902; Pub. L. 106–159, 113 Stat. 1748; and 49 CFR 1.87.

■ 4. Revise § 368.T3(d) to read as follows:

§ 368.T3 Starting the application process: URS online application.

* * * * *

(d) This section is in effect from December 12, 2015 through January 13, 2017.

PART 390—FEDERAL MOTOR CARRIER SAFETY REGULATIONS; GENERAL

■ 5. The authority citation for part 390 continues to read as follows:

Authority: 49 U.S.C. 504, 508, 31132, 31133, 31134, 31136, 31137, 31144, 31151, 31502; sec. 114, Pub. L. 103–311, 108 Stat. 1673, 1677, 1678; sec. 212, 217, Pub. L. 106–159, 113 Stat. 1748, 1766, 1767; sec. 229, Pub. L. 106–159 (as transferred by sec. 4115 and amended by secs. 4130–4132, Pub. L. 109–59, 119 Stat. 1144, 1726, 1743–44); sec. 4136, Pub. L. 109–59, 119 Stat. 1144, 1745; sections 32101(d) and 32934, Pub. L. 112–141, 126 Stat. 405, 778, 830; sec. 2, Pub. L. 113–125, 128 Stat. 1388; and 49 CFR 1.87.

■ 6. Revise § 390.T200(a) and (d) to read as follows:

§ 390.T200 USDOT Registration.

(a) *Purpose.* This section establishes who must register with FMCSA using the Form MCSA–1, the URS online application, beginning on December 12, 2015 and continuing through January 13, 2017.

* * * * *

(d) *Effective period.* This section is in effect from December 12, 2015, through January 13, 2017.

Issued under authority delegated in 49 CFR 1.87 on: July 14, 2016.

T.F. Scott Darling, III,

Acting Administrator.

[FR Doc. 2016–17461 Filed 7–27–16; 8:45 am]

BILLING CODE 4910–EX–P

Proposed Rules

Federal Register
Vol. 81, No. 145
Thursday, July 28, 2016

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF JUSTICE

Executive Office for Immigration Review

8 CFR Parts 1003, 1208

[EOIR Docket No. 170P; AG Order No. 3706–2016]

RIN 1125–AA68

Motions To Reopen Removal, Deportation, or Exclusion Proceedings Based Upon a Claim of Ineffective Assistance of Counsel

AGENCY: Executive Office for Immigration Review, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Justice (Department) is proposing to amend the regulations of the Executive Office for Immigration Review (EOIR) by establishing procedures for the filing and adjudication of motions to reopen removal, deportation, and exclusion proceedings based upon a claim of ineffective assistance of counsel. This proposed rule is in response to *Matter of Compean, Bangaly & J–E–C–,* 25 I&N Dec. 1 (A.G. 2009), in which the Attorney General directed EOIR to develop such regulations. The Department also proposes to amend the EOIR regulations that provide that ineffective assistance of counsel may constitute extraordinary circumstances that may excuse the failure to file an asylum application within 1 year after the date of arrival in the United States.

DATES: Written comments must be postmarked and electronic comments must be submitted on or before September 26, 2016.

ADDRESSES: You may submit comments, identified by EOIR Docket No. 170P, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.
- *Mail:* Jean King, General Counsel, Office of the General Counsel, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 2600, Falls Church, VA 22041. To ensure proper handling, please reference EOIR Docket No. 170P on your correspondence. This mailing address may also be used for paper, disk, or CD–ROM submissions.
- *Hand Delivery/Courier:* Jean King, General Counsel, Office of the General Counsel, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 2600, Falls Church, VA 22041. Contact Telephone Number (703) 305–0470.

FOR FURTHER INFORMATION CONTACT: Jean King, General Counsel, Office of the General Counsel, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 2600, Falls Church, VA 22041, telephone (703) 305–0470 (not a toll-free call).

SUPPLEMENTARY INFORMATION:

I. Public Participation

Interested persons are invited to participate in this rulemaking by submitting written data, views, or arguments on all aspects of this rule. The Department also invites comments that relate to the economic, environmental, or federalism effects that might result from this rule. Comments that will provide the most assistance to the Department in developing these procedures will reference a specific portion of the rule, explain the reason for any recommended change, and include data, information, or authority that support such recommended change.

All submissions received should include the agency name and EOIR Docket No. 170P for this rulemaking. Please note that all comments received are considered part of the public record and made available for public inspection at *http://www.regulations.gov.* Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You also must prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted on *http://www.regulations.gov.*

Personal identifying information and confidential business information identified as set forth above will be placed in the agency's public docket file, but not posted online. To inspect the agency's public docket file in person, you must make an appointment with agency counsel. Please see the **FOR FURTHER INFORMATION CONTACT** section above for agency counsel's contact information.

The reason that EOIR is requesting electronic comments before midnight Eastern Time on the day the comment period closes is because the inter-agency *Regulations.gov*/Federal Docket Management System (FDMS), which receives electronic comments, terminates the public's ability to submit comments at midnight on the day the comment period closes. Commenters in time zones other than Eastern may want to take this fact into account so that their electronic comments can be received. The constraints imposed by the *Regulations.gov*/FDMS system do not apply to U.S. postal comments, which will be considered as timely filed if they are postmarked before midnight on the day the comment period closes.

II. Executive Summary

This proposed rule would establish standards for adjudicating motions to reopen based on ineffective assistance of counsel in immigration proceedings before the immigration judges and the Board of Immigration Appeals (Board or BIA). The Board has addressed reopening proceedings based on ineffective assistance of counsel in *Matter of Lozada,* 19 I&N Dec. 637 (BIA 1988), and *Matter of Assaad,* 23 I&N Dec. 553 (BIA 2003). In *Matter of Compean, Bangaly, & J–E–C–,* 24 I&N Dec. 710 (A.G. 2009) (*Compean I*), Attorney General Mukasey overturned, in part, the Board's decisions in *Matter of Lozada* and *Matter of Assaad,* and provided a new administrative framework for adjudicating motions to reopen based on ineffective assistance of counsel. However, in *Matter of Compean, Bangaly, & J–E–C–,* 25 I&N Dec. 1 (A.G. 2009) *(Compean II),* Attorney General Holder vacated *Compean I,* and directed EOIR to develop a proposed rule pertaining to such motions. Accordingly, the Department of Justice (Department) has drafted this proposed rule.

Under this proposed rule, an individual seeking to reopen his or her immigration proceedings would have to establish that the individual was subject to ineffective assistance of counsel and that, with limited exceptions, he or she suffered prejudice as a result. The proposed rule would provide guidelines for determining when counsel's conduct was ineffective, and when an individual suffered prejudice. Under the proposed rule, a motion to reopen based on ineffective assistance of counsel would be required to include: (1) An affidavit, or a written statement executed under the penalty of perjury, providing certain information; (2) a copy of any applicable representation agreement; (3) evidence that prior counsel was notified of the allegations and of the filing of the motion; and (4) evidence that a complaint was filed with the appropriate disciplinary authorities. The proposed rule would permit adjudicators, in exercises of discretion committed exclusively to EOIR, to excuse noncompliance with these requirements in limited circumstances. The proposed rule would also provide that deadlines for motions to reopen can be equitably tolled in certain instances where the motion is based on ineffective assistance of counsel.

The Department believes that this proposed rule would promote consistency in the reopening of EOIR proceedings based on ineffective assistance of counsel, thereby helping to ensure the integrity and fairness of those proceedings. Given the importance of the issues involved, the Department believes it is important for the public to be able to participate in formulating the framework for reopening proceedings based on ineffective assistance of counsel.

III. Analysis of the Motion To Reopen Provisions in Proposed § 1003.48

The Immigration and Nationality Act ("Act" or "INA") provides the Attorney General with extensive authority relating to proceedings before the immigration courts and the Board. The Act provides the Attorney General with the authority to promulgate regulations governing such proceedings. *See* INA 103(g)(2). The Act further provides the Attorney General with the broad authority to reopen proceedings and recognizes her existing authority in this area. *See* INA 240(c)(7) (permitting a motion to reopen within 90 days of the date on which a final administrative order of removal is entered); INA 240(b)(5)(C) (granting an alien 180 days to seek reopening in order to rescind a removal order entered *in absentia,* and providing no time limit where the alien did not receive notice of the immigration hearing or was in custody and the failure to appear was through no fault of the alien).[1] The Supreme Court also has long recognized the broad discretion accorded the Attorney General to grant or deny motions to reopen proceedings. *See INS* v. *Doherty,* 502 U.S. 314, 323 (1992) ("The granting of a motion to reopen is thus discretionary, and the Attorney General has 'broad discretion' to grant or deny such motions.") (internal citation omitted); *accord INS* v. *Abudu,* 485 U.S. 94, 105–06 (1988); *INS* v. *Rios-Pineda,* 471 U.S. 444, 449 (1985); *Matter of Coelho,* 20 I&N Dec. 464, 471–72 (BIA 1992).[2] Under the delegated authority of the Attorney General, the Board has consistently permitted the reopening of immigration proceedings based upon a claim of ineffective assistance of counsel. *See Matter of Assaad,* 23 I&N Dec. at 558; *Matter of Lozada,* 19 I&N Dec. at 639–40. The Department believes that, in appropriate cases, reopening immigration proceedings based upon a claim of ineffective assistance of counsel continues to be a permissible exercise of the Attorney General's broad discretion.

Immigration proceedings are civil proceedings with high stakes, including the potential removal from the United States of an individual with long-standing family or other ties, or the grant or denial of relief or protection to an individual who claims to fear harm in his or her native country. *See, e.g., Aris* v. *Mukasey,* 517 F.3d 595, 600 (2d Cir. 2008); *Hernandez-Gil* v. *Gonzales,* 476 F.3d 803, 806 (9th Cir. 2007). Considering the serious consequences that may result from immigration proceedings, the Attorney General believes that it is paramount to ensure the integrity and fairness of such proceedings. The Attorney General therefore proposes to exercise her authority and discretion to regulate the administrative process of immigration proceedings before the immigration courts and the Board by codifying an administrative remedy for individuals who were in removal, deportation, or exclusion proceedings before EOIR and were subject to ineffective assistance of counsel.[3]

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[1] The Act's provisions relating to motions to reopen took effect in 1997. Motions to reopen immigration proceedings had previously been permitted by regulation. *See generally Dada* v. *Mukasey,* 554 U.S. 1, 12–15 (2008).

[2] The Act imposes requirements that must be met for a motion to reopen to be granted. *See, e.g.,* INA 240(c)(7)(B) ("The motion to reopen shall state the new facts that will be proven at a hearing to be held if the motion is granted, and shall be supported by affidavits or other evidentiary material."). The Act's implementing regulations elaborate on these requirements. *See* 8 CFR 1003.23(b)(3) ("A motion to reopen will not be granted unless the Immigration Judge is satisfied that evidence sought to be offered is material and was not available and could not have been discovered or presented at the former hearing."); 8 CFR 1003.2(c)(1) ("A motion to reopen proceedings shall not be granted unless it appears to the Board that evidence sought to be offered is material and was not available and could not have been discovered or presented at the former hearing[.]"); *cf.* 8 CFR 1003.23(b)(1) ("An Immigration Judge may upon his or her own motion at any time, or upon motion of the Service or the alien, reopen or reconsider any case in which he or she has made a decision, unless jurisdiction is vested with the Board of Immigration Appeals."); 8 CFR 1003.2(a) ("The Board may at any time reopen or reconsider on its own motion any case in which it has rendered a decision."); *Matter of J–J–,* 21 I&N Dec. 976, 984 (BIA 1997) ("Notwithstanding the statutorily mandated restrictions, the Board retains limited discretionary powers under the regulations to reopen or reconsider cases on our own motion. . . . The power to reopen on our own motion is not meant to be used as a general cure for filing defects or to otherwise circumvent the regulations, where enforcing them might result in hardship.") (internal citation omitted).

[3] The Department notes that there is currently a split among the circuits regarding whether there is a constitutionally-based right to effective counsel in immigration proceedings. *Compare, e.g., Lin Xing Jiang* v. *Holder,* 639 F.3d 751, 755 (7th Cir. 2011) ("No statute or constitutional provision entitles an alien who has been denied effective assistance of counsel to reopen the proceedings on the basis of that denial. This Circuit has recognized, nevertheless, that the denial of effective assistance of counsel may under certain circumstances violate the due process guarantee of the Fifth Amendment.") (brackets, ellipsis, and internal quotation marks and citation omitted); *Fadiga* v. *Att'y Gen.,* 488 F.3d 142, 155 (3d Cir. 2007) ("A claim of ineffective assistance of counsel in removal proceedings is cognizable under the Fifth Amendment—*i.e.,* as a violation of that amendment's guarantee of due process."), *Zeru* v. *Gonzales,* 503 F.3d 59, 72 (1st Cir. 2007) ("While aliens in deportation proceedings do not enjoy a Sixth Amendment right to counsel, they have due process rights in deportation proceedings."), *and Tang* v. *Ashcroft,* 354 F.3d 1192, 1196 (10th Cir. 2003) ("While an alien does not have a right to appointed counsel, he does have a Fifth Amendment right to a fundamentally fair proceeding."), *with Rafiyev* v. *Mukasey,* 536 F.3d 853, 861 (8th Cir. 2008) ("[W]e hold that there is no constitutional right under the Fifth Amendment to effective assistance of counsel in a removal proceeding."). It is beyond the scope of this proposed rule to address whether there is a constitutionally-based right to effective assistance of counsel in immigration proceedings. Rather, this rule is limited to providing an administrative

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The proposed rule would establish procedures and substantive requirements for the filing and adjudication of motions to reopen removal, deportation, and exclusion proceedings before the immigration judges and the Board based upon a claim of ineffective assistance of counsel. The rule would build on procedures, established in *Matter of Lozada* and *Matter of Assaad,* governing motions to reopen based upon a claim of ineffective assistance of counsel.

Matter of Lozada, decided by the Board in 1988, established a three-step procedure for individuals moving to reopen their deportation proceedings—which are now known as removal proceedings—based upon a claim of ineffective assistance of counsel. These three steps are commonly referred to as the *Lozada* requirements or *Lozada* factors, and they provide a "basis for assessing the substantial number of claims of ineffective assistance of counsel that come before the Board." *Matter of Lozada,* 19 I&N Dec. at 639. First, "[a] motion based upon a claim of ineffective assistance of counsel should be supported by an affidavit attesting to the relevant facts," including "a statement that sets forth in detail the agreement that was entered into with former counsel with respect to the actions to be taken [in the relevant proceeding] and what counsel did or did not represent to the [individual] in this regard." *Id.* Second, "former counsel must be informed of the allegations and allowed the opportunity to respond," and that response (or lack thereof) should accompany the motion. *Id.* Third, "the motion should reflect whether a complaint has been filed with the appropriate disciplinary authorities regarding such representation, and if not, why not." *Id.*

In *Matter of Lozada,* the Board also noted specifically that "[l]itigants are generally bound by the conduct of their attorneys, absent egregious circumstances." *Id.* (citing *LeBlanc* v. *INS,* 715 F.2d 685 (1st Cir. 1983)); *see also Matter of B–B–,* 22 I&N Dec. 309, 310–11 (BIA 1998). In denying the ineffective assistance claim in *Matter of Lozada,* the Board noted that "[n]o such egregious circumstances have been established in this case." *Matter of Lozada,* 19 I&N Dec. at 639.

The Board also required, in *Matter of Lozada,* that the individual filing the motion establish prejudice. *See id.* at 638, 640. The Board did not set forth a specific standard for prejudice, but simply noted that "no prejudice was shown to have resulted from prior counsel's" conduct in that case. *Id.* at 640.

For over 20 years since the Board's decision, *Matter of Lozada* has provided a workable administrative framework for adjudicating ineffective assistance claims in what are now known as removal proceedings. Thus, *Matter of Lozada* serves as a solid starting point for setting up a framework for this proposed rule. This framework affords relief to an individual in removal, deportation, or exclusion proceedings harmed by his or her attorney's ineffectiveness and at the same time takes into consideration countervailing concerns regarding abuse of the legal process and delay of immigration proceedings.

The Federal courts of appeals have generally endorsed the *Lozada* requirements. In doing so, courts have recognized the important policy considerations those requirements embody. *See, e.g., Beltre-Veloz* v. *Mukasey,* 533 F.3d 7, 10 (1st Cir. 2008) ("[The *Matter of Lozada*] framework . . . is designed to screen out frivolous, stale, and collusive claims."); *Patel* v. *Gonzales,* 496 F.3d 829, 831–32 (7th Cir. 2007) ("The *Lozada* requirements reduce the potential for abuse by providing information from which the BIA can assess whether an ineffective assistance claim has enough substance to warrant the time and resources necessary to resolve the claim on its merits."); *Reyes* v. *Ashcroft,* 358 F.3d 592, 597 (9th Cir. 2004) ("We presume, as a general rule, that the Board does not abuse its discretion when it obligates [individuals] to satisfy *Lozada's* literal requirements."); *Betouche* v. *Ashcroft,* 357 F.3d 147, 150 (1st Cir. 2004) (suggesting that *Matter of Lozada* provides "fair and efficacious techniques for screening out, *ab initio,* the numerous groundless and dilatory claims routinely submitted in these cases."); *Lo* v. *Ashcroft,* 341 F.3d 934, 937 (9th Cir. 2003) (". . . *Lozada's* policy goals . . . are to provide a framework within which to assess the *bona fides* of the substantial number of ineffective assistance claims asserted, to discourage baseless allegations and meritless claims, and to hold attorneys to appropriate standards of performance.").

While the Federal courts of appeals have generally endorsed the *Lozada* requirements, several courts have adopted varying interpretations for determining compliance with the *Lozada* requirements, establishing prejudice, and applying equitable tolling to the filing deadlines for motions to reopen based upon a claim of ineffective assistance of counsel. As discussed below, the courts of appeals have differed on what circumstances, if any, may excuse noncompliance with the *Lozada* requirements. For example, some courts have been flexible in applying the *Lozada* requirements where, in the court's view, strict compliance is not necessary to achieve the requirements' purpose. *See, e.g., Morales Apolinar* v. *Mukasey,* 514 F.3d 893, 896 (9th Cir. 2008) ("In practice, we have been flexible in our application of the *Lozada* requirements. The *Lozada* factors are not rigidly applied, especially where their purpose is fully served by other means."); *Xu Yong Lu* v. *Ashcroft,* 259 F.3d 127, 132–34 (3d Cir. 2001) (concluding that the *Lozada* requirements are "a reasonable exercise of the Board's discretion," *id.* at 132, but stressing "that the failure to file a [bar] complaint is *not* fatal if a petitioner provides a reasonable explanation for his or her decision," *id.* at 134) (emphasis in original); *cf. Patel,* 496 F.3d at 831 (holding that "[t]he BIA is free to deny motions to reopen for failure to comply with *Lozada* as long as it does not act arbitrarily"). One court has found that there are circumstances where compliance with the requirements is unnecessary. *See, e.g., Escobar-Grijalva* v. *INS,* 206 F.3d 1331, 1335 (9th Cir. 2000) (finding that there is no need to comply with *Matter of Lozada* where the record establishes on its face ineffective assistance of counsel).

The Federal courts of appeals have also proposed varying standards for prejudice. Some courts have required a strict standard for evaluating prejudice. *See, e.g., Sako* v. *Gonzales,* 434 F.3d 857, 864 (6th Cir. 2006) (requiring the individual filing the motion to "establish that, but for the ineffective assistance of counsel, he would have been entitled to continue residing in the United States"). Other courts have applied a standard similar to that established by *Strickland* v. *Washington,* 466 U.S. 668, 694 (1984), which held that prejudice exists when there is a "reasonable probability that, but for counsel's unprofessional errors, the result of the proceeding would have been different." *See, e.g., Fadiga* v. *Att'y Gen.,* 488 F.3d 142, 158–59 (3d Cir.

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remedy under appropriate circumstances based on the Attorney General's statutory authority and discretion. We note, however, that Attorney General Holder's order in *Compean II,* 25 I&N Dec. at 3, provided that nothing in that order would affect the litigating positions of the Department, and the Department has consistently argued before the Supreme Court that there is no constitutional right to effective assistance of counsel in immigration proceedings. *E.g.,* Brief for Respondent on Petition for a Writ of Certiorari at 14 n.3, *Mata* v. *Holder,* 135 S. Ct. 1039 (2015) (No. 14–185). Nothing in the proposed regulations affects this position.

2007) (agreeing that *Strickland's* "reasonable probability" standard is appropriate in the context of removal proceedings); *Obleshchenko* v. *Ashcroft,* 392 F.3d 970, 972 (8th Cir. 2004) (characterizing the court's prejudice standard as "akin" to the *Strickland* test).

In addition, while the courts of appeals that have reached the issue have permitted the equitable tolling of filing deadlines for untimely motions to reopen based upon claims of ineffective assistance of counsel, some courts have not yet fully addressed whether these deadlines can be equitably tolled.[4] *Compare, e.g., Barry* v. *Mukasey,* 524 F.3d 721, 724 (6th Cir. 2008) ("Equitable tolling may apply when a petitioner has received ineffective assistance of counsel.") (internal quotation marks omitted), *with Neves* v. *Holder,* 613 F.3d 30, 36 (1st Cir. 2010) (stating that "[w]e assume arguendo, but do not decide, that the time and number limits on motions to reopen are subject to equitable tolling"). There is also a lack of uniformity among the courts regarding the precise requirements and standards that an individual must meet to establish due diligence in order to be eligible for equitable tolling. *Compare, e.g., Singh* v. *Gonzales,* 491 F.3d 1090, 1096 (9th Cir. 2007) (providing that the filing deadline "is [equitably] tolled until the petitioner 'definitively learns' of counsel's fraud," if the petitioner acted with due diligence), *with Patel* v. *Gonzales,* 442 F.3d 1011, 1016 (7th Cir. 2006) (providing that "[e]quitable tolling requires a court to consider whether a reasonable person in the plaintiff's position would have been aware of the *possibility* that he had suffered an injury") (internal quotation marks omitted).

The purpose of this proposed rule is to establish uniform procedural and substantive requirements for the filing of motions to reopen based upon a claim of ineffective assistance of counsel and to provide a uniform standard for adjudicating such motions. Like *Matter of Lozada* and its progeny, this proposed rule would provide an "objective basis from which to assess the veracity of the substantial number of ineffective assistance claims," would "hold attorneys to appropriate standards of performance," and would "ensure both that an adequate factual basis exists in the record for an ineffectiveness [motion] and that the [motion] is a legitimate and substantial one." *Tamang* v. *Holder,* 598 F.3d 1083, 1090 (9th Cir. 2010) (discussing the goals behind *Matter of Lozada*) (internal quotation marks omitted). While allowing for some flexibility, the proposed rule would clarify the specific kinds of evidence and documentation to be submitted in support of motions to reopen based upon a claim of ineffective assistance of counsel. The filing requirements described in this rule would serve to guide an individual filing a motion to reopen in providing evidence necessary for a determination as to whether his or her counsel was ineffective. As the Board stated in *Matter of Lozada,* "[t]he high standard announced here is necessary if we are to have a basis for assessing the substantial number of claims of ineffective assistance of counsel that come before the Board. Where essential information is lacking, it is impossible to evaluate the substance of such claim." *Matter of Lozada,* 19 I&N Dec. at 639.

This proposed rule would add new § 1003.48 to title 8 of the Code of Federal Regulations ("regulations"). New § 1003.48 would provide the filing and evidentiary requirements for motions to reopen based upon a claim of ineffective assistance of counsel. This section would also incorporate standards for evaluating whether an individual has established that he or she (1) acted with due diligence for the purpose of determining the applicability of equitable tolling and (2) was prejudiced by prior counsel's conduct. In addition, this proposed rule would add a cross-reference to new § 1003.48 to the current regulations governing motions to reopen proceedings and to rescind orders of removal, deportation, or exclusion entered *in absentia.*

The Department notes that the Board has consistently permitted the reopening of proceedings based upon a claim of ineffective assistance of counsel. *See Matter of Assaad,* 23 I&N Dec. at 558.[5] The requirements in proposed new § 1003.48 would be in addition to the general requirements for reopening provided in section 240(c)(7) of the Act and §§ 1003.2 and 1003.23 of the regulations. Thus, motions to reopen proceedings based upon a claim of ineffective assistance of counsel would need to meet the general requirements for reopening in proposed §§ 1003.2 and 1003.23, as well as the procedural and substantive requirements for such motions at proposed § 1003.48. The Board and the immigration judges, moreover, have broad authority to grant or deny a motion in the exercise of discretion, and this includes the discretion to deny a motion even if the party moving has presented a *prima facie* case for relief. *See* 8 CFR 1003.2(a), 1003.23(b)(3); *see also Abudu,* 485 U.S. at 105 (explaining that, even where an individual filing a motion to reopen has presented a *prima facie* case for relief, the Board may deny the motion if the movant would not be entitled to the discretionary relief ultimately at issue).

A. Applicability

The proposed provisions of the rule addressing motions to reopen based upon a claim of ineffective assistance of counsel would cover conduct that occurred only after removal, deportation, or exclusion proceedings have commenced with the immigration courts.[6] With the exception discussed below, the proposed provisions of § 1003.48 would not apply to motions to reopen proceedings before the immigration judge or the Board based on counsel's conduct before another administrative or judicial body, including before, during the course of, or after the conclusion of immigration proceedings. This includes conduct that was immigration-related or that occurred before the U.S. Department of Homeland Security (DHS) or another government agency. *See, e.g., Contreras* v. *Att'y Gen.,* 665 F.3d 578, 585–86 (3d Cir. 2012) (declining to find ineffective assistance of counsel in the preparation and filing of a visa petition where counsel's conduct "did not compromise the fundamental fairness of" subsequent removal proceedings); *Balam-Chuc* v. *Mukasey,* 547 F.3d 1044, 1051 (9th Cir. 2008) (same where counsel's conduct "[did] not relate to the fundamental fairness of an ongoing proceeding"). The reason for this limitation is that the Board and the immigration judges are generally not in a position to provide a remedy in a situation where an attorney's performance before another administrative or judicial body is alleged to be ineffective. Rather, a request for a remedy in such a situation would be more appropriately directed to that administrative or judicial body before which the alleged ineffective assistance occurred. *Cf. Rivera* v. *United States,* 477 F.2d 927, 928 (3d Cir. 1973) (holding that, where the petitioner's appeal had been dismissed because his attorney failed to file a brief, the petitioner's remedy was through a motion in the court of appeals requesting that the mandate be recalled to determine whether the appeal should be reinstated, not through a motion in the district court); *United States* v. *Winterhalder,* 724 F.2d 109, 111 (10th Cir. 1983) (same).

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[4] Equitable tolling refers to "[t]he doctrine that the statute of limitations will not bar a claim if the plaintiff, despite diligent efforts, did not discover the injury until after the limitations period had expired." *Black's Law Dictionary* 579 (8th ed. 2004).

[5] Section 240 of the Act is applicable only to removal proceedings (which are initiated on or after April 1, 1997), but, by far, most motions to reopen are filed in removal proceedings. For clarity, we note that in deportation and exclusion proceedings, and all other types of proceedings before the immigration judges and the Board, motions to reopen are governed exclusively by the Attorney General's regulations in 8 CFR 1003.2 and 1003.23, not by section 240 of the Act.

[6] For purposes of this rule, included as "removal, deportation, or exclusion proceedings" would be asylum-only and withholding-only proceedings, given that those proceedings are "conducted in accordance with the same rules of procedure as [removal proceedings]." 8 CFR 1208.2(c)(3)(i). This rule would not apply in bond proceedings. However, in bond proceedings, after an immigration judge makes an initial bond redetermination, an individual can request, in writing, that the immigration judge make "a subsequent bond redetermination . . . [based] upon a showing that the alien's circumstances have changed materially since the prior bond redetermination." 8 CFR 1003.19(e). In addition, this rule would not apply in practitioner discipline proceedings conducted under 8 CFR part 1003 subpart G.

The proposed motion provisions in § 1003.48 would provide for one explicit exception to the limitation on the Board's authority to provide a remedy for ineffective assistance of counsel before another administrative or judicial body. The exception would be with respect to a claim that counsel was ineffective for failing to file a timely petition for review of a Board decision with the appropriate court of appeals. Under the proposed rule at § 1003.48(c), an individual could file a motion to reopen with the Board in such a situation, and the Board would have discretion to reopen proceedings to address such a claim. The reason for allowing such a motion is that the failure to file a timely petition for review leaves the court of appeals without any jurisdiction to address the claim of ineffectiveness given that the 30-day deadline for filing a petition for review is mandatory and jurisdictional. *See* INA 242(a)(1), (b)(1); *see, e.g., Ortiz-Alfaro* v. *Holder,* 694 F.3d 955, 958 (9th Cir. 2012); *Ruiz-Martinez* v. *Mukasey,* 516 F.3d 102, 117–18 (2d Cir. 2008); *Dakane* v. *U.S. Att'y. Gen.,* 399 F.3d 1269, 1272 n. 3 (11th Cir. 2004); *Magtanong* v. *Gonzales,* 494 F.3d 1190, 1191 (9th Cir. 2007). This exception is consistent with the general principles expressed in both *Compean I* and *Compean II;* in both decisions, the Attorney General contemplated that the Board could provide a remedy for ineffective assistance that occurred after the issuance of a final order of removal. *See Compean I,* 24 I&N Dec. at 740 (stating that "the [view] I adopt today . . . is that the Board has jurisdiction to consider deficient performance claims even where they are predicated on lawyer conduct that occurred after a final order of removal has been entered"); *Compean II,* 25 I&N Dec. at 3 (noting that, "prior to *Compean*[*I*], the Board itself had not resolved whether its discretion to reopen removal proceedings includes the power to consider claims of ineffective assistance of counsel based on conduct of counsel that occurred after a final order of removal had been entered," and stating that "I resolve the question in the interim by concluding that the Board does have this discretion, and I leave it to the Board to determine the scope of such discretion").

For his or her case to be reopened, an individual filing the motion based on failure to file a timely petition for review would have to comply with the requirements of § 1003.48(b)(1)–(3) (affidavit, notice to counsel, and complaint filed with the appropriate disciplinary authorities), described in more detail below. Under § 1003.48(c)(2), in order to establish that counsel acted ineffectively, the individual would have to establish that counsel had agreed to file a petition for review but failed to do so. To meet this burden, the individual would have to submit a representation agreement making clear that the scope of representation included the filing of a petition for review, or would have to otherwise establish that the scope of representation included the filing of a petition for review.

The proposed motion provisions would only apply to the conduct of certain individuals. With the exception discussed below, these provisions would cover only the conduct of attorneys and accredited representatives as defined in part 1292 of title 8 of the Code of Federal Regulations. The reason for such a limitation is that attorneys and accredited representatives are governed by rules of professional conduct and have skills, including knowledge of immigration laws and procedures, which are directly related to furthering the interests that individuals and the government have in fair and accurate immigration proceedings. *See, e.g., Hernandez* v. *Mukasey,* 524 F.3d 1014, 1018–20 (9th Cir. 2008) (noting that, in contrast to the law's treatment of attorneys possessing particular skills and governed by specific professional standards, "the law has never presumed that [the participation of non-attorney 'immigration consultants'] is necessary or desirable to ensure fairness in removal proceedings," *id.* at 1019, and that, if "an individual . . . knowingly relies on assistance from individuals not authorized to practice law, such a voluntary choice will not support a due process claim based on ineffective assistance of counsel," *id.* at 1020). With limited exceptions, a person who is not an attorney or accredited representative is not permitted to represent individuals in proceedings before the immigration courts or the Board. *See* 8 CFR 1292.1(a)(1)–(5). Moreover, the regulations require the immigration judge to advise individuals in removal proceedings of their right to representation, at no expense to the government, by counsel of their choice authorized to practice in the proceedings, and specifically require that individuals in proceedings be advised of the availability of pro bono legal services and receive a list of such services. *See* 8 CFR 1003.16, 1003.61, 1240.10(a)(1).

However, this proposed rule would recognize that, sometimes, a person who is not an attorney or accredited representative may lead an individual in removal, deportation, or exclusion proceedings to believe that the person is an attorney or representative, and that the individual in proceedings, as a result of that mistaken belief, may retain that person to represent him or her in such proceedings. When this occurs, in assessing whether to reopen proceedings, the immigration judge or the Board would evaluate on a case-by-case basis whether it was reasonable for the individual in such proceedings to believe that the person in question was indeed an attorney or an accredited representative, and whether he or she then retained that person. *See* §§ 1003.23(b)(4)(v), 1003.48(a)(1). In evaluating these questions, the immigration judge or the Board could consider, among others, the following inquiries: whether, and the extent to which, the person held himself or herself out as an attorney or accredited representative; whether the individual in proceedings knowingly relied on the assistance of the person not authorized to practice law; and the extent of the representation, including whether the person appeared in the immigration proceedings or completed, signed, or submitted documents or evidence in such proceedings on behalf of the individual.

B. Effective Date

In addition to the above limitations, the proposed provisions of § 1003.48 would apply only to motions to reopen proceedings based upon a claim of ineffective assistance of counsel filed with the immigration courts or the Board on or after the effective date of the final rule.

C. Proposed Requirements in § 1003.48 for Filing a Motion To Reopen Based Upon a Claim of Ineffective Assistance of Counsel

The proposed rule at § 1003.48 would provide filing and evidentiary requirements for motions to reopen based upon a claim of ineffective assistance of counsel. In order to succeed in a motion to reopen, the individual filing the motion would have to submit evidence both that prior counsel's conduct was ineffective and that the individual was prejudiced as a result of counsel's ineffective assistance.

With respect to the specific conduct that would amount to ineffective assistance in immigration proceedings, this rule would not set any bright line standards, or an enumerated list, of what specific conduct would amount to ineffective assistance in immigration proceedings. Rather, the proposed rule would provide, at § 1003.48(a)(2), that "[a] counsel's conduct constitutes ineffective assistance of counsel if the conduct was unreasonable, based on the facts of the particular case, viewed as of the time of the conduct."

This provision, in calling for an inquiry based on the reasonableness of the counsel's conduct, viewed when the conduct occurred, would be based on the Supreme Court's holding in *Strickland.* There, the Court stated that "[n]o particular set of detailed rules for counsel's conduct can satisfactorily take account of the variety of circumstances faced by . . . counsel or the range of legitimate decisions regarding how best to represent a [client]." *Strickland,* 466 U.S. at 688–89. Rather, for an attorney's representation to constitute ineffective assistance, the representation "must . . . [fall] below an objective standard of reasonableness," *id.* at 688, judged "on the facts of the particular case, [and] viewed as of the time of counsel's conduct," *id.* at 690; *see also Wong* v. *Belmontes,* 558 U.S. 15, 16–17 (2009) (per curiam) (citing *Strickland,* 466 U.S. at 687–89).

Under this proposed provision, a tactical decision would not be ineffective assistance if the decision was reasonable when it was made, even if it proved unwise in hindsight. *See Strickland,* 466 U.S. at 689 (stating that "[a] fair assessment of attorney performance requires that every effort be made to eliminate the distorting effects of hindsight"); *Mena-Flores* v. *Holder,* 776 F.3d 1152, 1169 (10th Cir. 2015) (stating that "[a]n attorney's objectively reasonable tactical decisions do not qualify as ineffective assistance"); *Jiang* v. *Mukasey,* 522 F.3d 266, 270 (2d Cir. 2008) (holding that "recommending [a] strategic decision [that ultimately does not succeed] does not constitute ineffective assistance of counsel"); *Magallanes-Damian* v. *INS,* 783 F.2d 931, 934 (9th Cir. 1986) (holding that the attorney's decision not to contest deportability, even if "unwise" in hindsight, was not ineffective assistance of counsel); *Rodriguez-Gonzalez* v. *INS,* 640 F.2d 1139, 1142 (9th Cir. 1981) (holding that a tactical "decision to forego challenging [an] accusation of entry without inspection . . . even if in hindsight unwise, does not constitute ineffective assistance"); *cf. Matter of Velasquez,* 19 I&N Dec. 377, 383 (BIA 1986) (stating that the attorney's "admissions [of factual allegations] and the concession of deportability were reasonable tactical actions," and thus were binding). Further, under this proposed provision, we expect that there would be "a strong presumption that counsel's conduct falls within the wide range of reasonable professional assistance." *Strickland,* 466 U.S. at 689.

The filing requirements described in proposed § 1003.48(b)(1)–(3) would serve to guide the individual filing the motion in providing the evidence necessary for a determination as to whether his or her counsel's conduct was ineffective. In order to demonstrate that counsel's conduct was ineffective, the motion should set forth clearly the particular circumstances underlying a given case. In order to prevail, the individual may need to submit documentary or other supporting evidence beyond that described in § 1003.48(b)(1)–(3). For example, additional evidence could include evidence of payment to prior counsel or an affidavit explaining what the individual in proceedings specifically disclosed to prior counsel, such as the individual's family ties or criminal history. Additional supporting evidence could also include written statements from current counsel or witnesses regarding prior counsel's conduct.

As discussed in detail in section E, in addition to demonstrating that prior counsel's conduct was ineffective, the individual filing the motion would have the burden of establishing that the individual was prejudiced as a result of that conduct. The requirement of providing evidence that the prior counsel was ineffective would be distinct from establishing prejudice as required in § 1003.48(b)(4). The Department cautions that the immigration judge or the Board would have the discretion to deny the motion without reaching the issue of prejudice, if the individual does not submit arguments or evidence establishing that the prior counsel's conduct was ineffective.

Proposed § 1003.48 would describe the required evidence to be included with a motion to reopen proceedings before the immigration judge or the Board based upon a claim of ineffective assistance of counsel. Section 1003.48(b)(1)(i) would require an individual to submit an affidavit, or a written statement executed under the penalty of perjury as provided in 28 U.S.C. 1746,[7] setting forth in detail the agreement that was entered into with prior counsel with respect to the actions to be taken by counsel, and what representations counsel did or did not make in this regard.

An affidavit is "[a] written or printed declaration or statement of facts, made voluntarily, and confirmed by the oath or affirmation of the party making it, taken before a person having authority to administer such oath or affirmation." *Black's Law Dictionary* 58 (6th ed. 1990). The "affidavit provides an exact, sworn recitation of facts, collected in one place . . . . [T]he affidavit requirement serves not only to focus the facts underlying the charge, but to foster an atmosphere of solemnity commensurate with the gravity of the claim." *Reyes,* 358 F.3d at 598 (ellipsis and brackets in original) (quoting *Keating* v. *Office of Thrift Supervision,* 45 F.3d 322, 327 (9th Cir. 1995)). The Department recognizes, however, that some individuals, particularly those who are unrepresented, may face burdens in complying with the technical requirements of an affidavit. For example, an unrepresented individual may be in detention and without ready access to an official with authority to administer an oath or affirmation. For that reason, § 1003.48(b)(1)(i) would permit the submission of a written statement, executed under the penalty of perjury as provided in 28 U.S.C. 1746, that does not meet the technical requirements of an affidavit. In addition, as described in more detail below, the Board or an immigration judge could, in an exercise of discretion committed solely to EOIR, excuse the requirement that the written statement be executed under the penalty of perjury in certain limited instances.

Proposed § 1003.48(b)(1)(ii) would provide that, in addition to the affidavit or written statement executed under the penalty of perjury, the individual filing the motion must submit a copy of any agreement entered into with prior counsel. If no agreement is provided, the individual would have to explain its absence in the affidavit or written statement, for example by describing his or her efforts to obtain the agreement from prior counsel. In addition, the individual would have to provide any reasonably available evidence on the scope of the agreement and the reasons for its absence, for example by providing evidence that the representation agreement was unwritten. The requirement to provide evidence of the agreement with prior counsel would help immigration judges and the Board to understand the "nature, scope, or substance" of the attorney's obligations, if any, to his or her client, and thus whether prior counsel was ineffective. *Beltre-Veloz,* 533 F.3d at 10; *see also Punzalan* v. *Holder,* 575 F.3d 107, 111–12 (1st Cir. 2009) (quoting *Beltre-Veloz,* 533 F.3d at 10); *Ruiz-Martinez,* 516 F.3d at 121 (rejecting an ineffective assistance of counsel claim because the individual filing the motion "did not set forth his agreement with his prior attorneys concerning what actions would be taken or what they did or did not represent in this regard").

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[7] Under 28 U.S.C. 1746, an unsworn declaration, certification, verification, or statement executed in the United States is deemed to be made under penalty of perjury if it includes the following words "in substantially the following form": "I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). . . . (Signature)."

Proposed § 1003.48(b)(2) would require an individual filing a motion to provide evidence that the counsel whose representation is claimed to have been ineffective has been informed of the allegations leveled against that counsel and that a motion to reopen alleging ineffective assistance of counsel would be filed on that basis. As discussed in *Matter of Lozada,* this requirement would mitigate the possibility of abuse by providing a "mechanism . . . for allowing former counsel . . . to present his version of events if he so chooses." 19 I&N Dec. at 639; *see Debeatham* v. *Holder,* 602 F.3d 481, 485–86 (2d Cir. 2010). Additionally, this "notice requirement [would] provide[ ] a mechanism by which the [immigration judge] may more accurately assess the merits of [an] ineffective assistance claim." *Reyes,* 358 F.3d at 599.

The Department notes that merely copying counsel on a complaint filed with the appropriate State bar or governmental authority would not be sufficient to meet the notice requirement; rather, the individual filing the motion would have to provide notice to his or her prior counsel in a separate written correspondence that a motion to reopen would be filed alleging ineffective assistance of counsel. With the motion, the individual would also have to provide evidence of the date he or she provided notice to prior counsel, and the manner in which this notice was provided, and the individual would have to include a copy of the correspondence to the attorney. The individual would also have to submit to the immigration court or the Board any subsequent response from prior counsel. This obligation would continue until such time as a decision is rendered on the motion.

Proposed § 1003.48(b)(3) would further require the individual filing the motion to file a complaint with the appropriate disciplinary authorities with respect to any violation of prior counsel's ethical or legal responsibilities. This requirement would help to monitor the legal profession and to assist the appropriate disciplinary authorities in considering and acting on instances of ineffective assistance of counsel. *See, e.g., Matter of Rivera,* 21 I&N Dec. 599, 603–05 (BIA 1996). Additionally, it would "highlight[ ] the standard[s] which should be expected of attorneys who represent persons in immigration proceedings, the outcome of which may, and often does, have enormous significance for the person." *Sswajje* v. *Ashcroft,* 350 F.3d 528, 533 (6th Cir. 2003) (quoting *Matter of Lozada,* 19 I&N Dec. at 639–40); *see also Reyes,* 358 F.3d at 596 (same). The requirement would "also serve[ ] to protect against collusion between alien and counsel in which 'ineffective' assistance is tolerated, and goes unchallenged by an alien before disciplinary authorities, because it results in a benefit to the alien in that delay can be a desired end, in itself, in immigration proceedings." *Matter of Rivera,* 21 I&N Dec. at 604; *see also Betouche,* 357 F.3d at 150 (recognizing the "significant prospect that entirely meritless and/or collusive ineffective assistance claims may be filed for purely dilatory purposes"); *Xu Yong Lu,* 259 F.3d at 133 (quoting *Matter of Rivera,* 21 I&N Dec. 599, on the purposes of the bar complaint requirement).

The proposed rule provides that the individual filing the motion would have to file the complaint against his or her representative with the appropriate disciplinary authorities. For an attorney, the individual would have to file the complaint with the relevant State licensing authority. For an accredited representative, the individual would have to file the complaint with the EOIR disciplinary counsel.[8] Where the individual filing the motion reasonably but erroneously believed a person to be an attorney or accredited representative and retained that person to represent him or her in the proceedings before the immigration judge or the Board, the individual would have to file the complaint with an appropriate State or local law enforcement agency (which in some States may include the State Attorney General's office) with authority over matters relating to the unauthorized practice of law or immigration-related fraud. If the individual filing the motion has any questions regarding determining the appropriate State or local enforcement agency with authority over such matters in proceedings before the immigration judges or the Board, he or she should contact the Fraud and Abuse Prevention Program in the Office of the General Counsel at EOIR at (703) 305–0470.

The individual filing the motion would have to submit a copy of the complaint and any correspondence from the disciplinary authority with his or her motion to the immigration court or the Board. In addition to filing the required complaint, the individual would not be precluded from taking any other actions to notify appropriate governmental or disciplinary authorities regarding the conduct of his or her prior counsel, accredited representative, or any person retained by the individual whom he or she reasonably but erroneously believed to be an attorney or accredited representative, and submitting evidence of such actions with his or her motion. In addition, the Department notes that this rule would not preclude the individual from taking any other actions to notify the appropriate governmental or disciplinary authorities regulating the unauthorized practice of law regarding any person not authorized to practice law.

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[8] Individuals in immigration proceedings are permitted representation of their choosing before EOIR and may be represented by an accredited representative. 8 CFR 1003.16, 1292.1. The proposed rule would require that complaints against accredited representatives be filed with the EOIR disciplinary counsel because EOIR is responsible for the accreditation process and the EOIR disciplinary counsel is responsible for investigating allegations of misconduct against accredited representatives appearing before the immigration courts and the Board. *See* 8 CFR 1003.104, 1292.2(d). The Department notes that the Board and some circuit courts have analyzed ineffective assistance of counsel claims without expressly addressing whether the *Matter of Lozada* requirements should be strictly applied to an accredited representative. *See, e.g., Matter of Zmijewska,* 24 I&N Dec. 87, 94–95 (BIA 2007); *Romero* v. *INS,* 399 F.3d 109, 112–13 (2d Cir. 2005). The Department has determined, however, that due to EOIR's ability to accredit and to discipline accredited representatives, an accredited representative should be treated the same as an attorney for purposes of determining ineffective representation. Thus, the Department has determined that the requirements for reopening based upon a claim of ineffective assistance of counsel should be applied to an accredited representative appearing in cases before the immigration judges or the Board in the same manner as the requirements are applied to an attorney.

The Department welcomes input from the public about the requirement to submit, with a motion to reopen, a complaint filed with the appropriate disciplinary authorities. As noted above, there are important policy reasons for this requirement, although the Department acknowledges certain countervailing concerns, as referenced by Attorney General Mukasey in *Compean I, see* 24 I&N Dec. at 737–38. The Department welcomes comments, including from State licensing authorities, regarding the efficacy of this requirement in assisting State licensing authorities in regulating the legal profession.

Finally, proposed § 1003.48(b) would require the individual filing the motion to comply with the existing requirements for motions to reopen in §§ 1003.2 and 1003.23. Sections 1003.2 and 1003.23 require the individual to submit evidence of what will be proven at the hearing if the motion is granted and to submit any appropriate applications for relief, supporting documentation, or other evidentiary material. For a motion based on ineffective assistance of counsel, this could include evidence that the filer's prior counsel failed to provide to the immigration judge or the Board, or other independent evidence, such as affidavits, applications for relief and supporting documentation, proffered testimony of potential witnesses, family history, country conditions, identity documentation, or criminal records or clearances.

After promulgation of this rule, the Department may publish additional information, such as in a fact sheet or other format, to assist the public in filing motions to reopen based upon a claim of ineffective assistance of counsel. Additionally, the Department will seek out opportunities to engage the public in an effort to inform individuals about the process. The Department welcomes input from the public regarding what type of information might best assist counsel and unrepresented individuals in the preparation and filing of such motions with the immigration courts and the Board as well as information and ideas on how best to engage impacted communities.

D. Compliance With the Filing Requirements in Proposed § 1003.48

As discussed above, the evidentiary requirements in proposed § 1003.48 would guide individuals in proceedings in providing the evidence necessary for a determination of whether the counsel's conduct was ineffective, and would assist the immigration judge and the Board in making this determination. *See generally Matter of Lozada,* 19 I&N Dec. at 639–40 (discussing how these evidentiary requirements assist the adjudicator in evaluating a claim of ineffective assistance of counsel); *Matter of Assaad,* 23 I&N Dec. at 556–57 (same); *Matter of Rivera,* 21 I&N Dec. at 603–07 (same).

Most circuits have required some level of compliance with *Matter of Lozada.* The First Circuit, for example, has generally required that the *Matter of Lozada* requirements be satisfied. *See, e.g., Georcely* v. *Ashcroft,* 375 F.3d 45, 51 (1st Cir. 2004) (noting that "[a]lthough we have hinted that full compliance with *Lozada's* requirements might be excused in an appropriate case, the *Lozada* requirements generally make sense") (internal citation omitted). The court in *Georcely* reasoned:

> It is all too easy after the fact to denounce counsel and achieve a further delay while that issue is sorted out. And in the absence of a complaint to the bar authorities, counsel may have all too obvious an incentive to help his client disparage the quality of the representation.

Id.; see also Punzalan, 575 F.3d at 111 ("The BIA acts within its discretion in denying motions to reopen that fail to meet the *Lozada* requirements as long as it does so in a non-arbitrary manner.") (internal quotation marks omitted); *Betouche,* 357 F.3d at 150–51 (setting forth reasons for the *Matter of Lozada* requirements).

The Seventh, Eighth, and Tenth Circuits have also generally required compliance, but have not yet determined whether they might overlook a lack of compliance with the *Matter of Lozada* requirements in an appropriate case. *See Patel,* 496 F.3d at 831 (noting that "[w]e have not expressly decided whether the BIA abuses its discretion by requiring strict compliance with *Lozada*"); *Habchy* v. *Gonzales,* 471 F.3d 858, 863 (8th Cir. 2006) (noting that the Eighth Circuit "has not ruled on whether a strict application of those requirements could constitute an abuse of discretion in certain circumstances," but stating that, "[a]t the very least, an [immigration judge] does not abuse his discretion in requiring substantial compliance with the *Lozada* requirements when it is necessary to serve the overall purposes of *Lozada*"); *Tang* v. *Ashcroft,* 354 F.3d 1192, 1196–97 (10th Cir. 2003) (stating that "[w]e not decide whether substantial compliance would be sufficient because Mr. Tang has made no attempt to comply with any of *Lozada's* requirements"); *see also Stroe* v. *INS,* 256 F.3d 498, 504 (7th Cir. 2001) (noting that "we have difficulty understanding how an alien who fails to comply with the Board's criteria can succeed in challenging its decision").

The Sixth Circuit has also required that individuals filing motions generally comply with all three *Lozada* requirements, noting that "[s]ound policy reasons support compliance" and the requirements "facilitate a more thorough evaluation by the BIA and discourage baseless allegations." *Hamid* v. *Ashcroft,* 336 F.3d 465, 469 (6th Cir. 2003) (internal quotation marks omitted); *see also Pepaj* v. *Mukasey,* 509 F.3d 725, 727 (6th Cir. 2007) ("An alien who fails to comply with *Lozada's* requirements forfeits her ineffective-assistance-of-counsel claim."). The Fifth Circuit also requires compliance with *Matter of Lozada. See Rodriguez-Manzano* v. *Holder,* 666 F.3d 948, 953 (5th Cir. 2012) (rejecting the argument that the court "should apply *Lozada* flexibly").

Other courts have adopted or indicated an approach under which full compliance may be excused in certain limited circumstances. In *Barry* v. *Gonzales,* 445 F.3d 741 (4th Cir. 2006), the court explained:

> [A]lthough *Lozada* provides a useful framework for assessing ineffective assistance claims, an alien's failure to satisfy all three requirements does not preclude appellate court review in every case. We will reach the merits of an ineffective assistance of counsel claim where the alien substantially complies with the *Lozada* requirements, such that the BIA could have ascertained that the claim was not frivolous and otherwise asserted to delay deportation. However, an alien who fails to satisfy any of the three *Lozada* requirements will rarely, if ever, be in substantial compliance.

Id. at 746; *cf. Dakane,* 399 F.3d at 1274 (requiring "substantial, if not exact, compliance with the procedural requirements of *Lozada*"); *Gbaya* v. *U.S. Att'y Gen.,* 342 F.3d 1219, 1222 & n. 2 (11th Cir. 2003) (stating that, given that the individual who filed the motion "failed to comply with at least two out of three *Lozada* requirements, [he] would not be in substantial compliance with *Lozada,*" *id.* at 1222 n.2, but not deciding "whether the BIA may enforce strict compliance with *Lozada* or must also accept substantial compliance," *id.* at 1222).

However, a few courts of appeals have gone further, excusing a lack of compliance in a greater variety of situations. Such courts have warned of the "inherent dangers . . . in applying a strict, formulaic interpretation of *Lozada*." *Rranci* v. *Att'y Gen.*, 540 F.3d 165, 173 (3d Cir. 2008) (ellipsis in original) (internal quotation marks omitted); *see also Yang* v. *Gonzales*, 478 F.3d 133, 142–43 (2d Cir. 2007) ("As to compliance with *Lozada* in relation to claims of ineffective assistance of counsel, we have not required a slavish adherence to the requirements, holding only that substantial compliance is necessary."). These courts of appeals have differed on what circumstances excuse the *Matter of Lozada* requirements, but have generally held that there must be a rational reason for excusing failure to comply with one or more of the requirements. For example, both the Ninth and Second Circuits have noted that the *Matter of Lozada* requirements should not be rigidly applied where their purpose is fully served by other means. *See, e.g., Morales Apolinar*, 514 F.3d at 896; *Piranej* v. *Mukasey*, 516 F.3d 137, 144–45 (2d Cir. 2008) (remanding to the Board because, although the individual filing the motion failed to submit an affidavit outlining his agreement with his prior counsel, a general retainer agreement may have satisfied the *Matter of Lozada* requirements).

The Ninth Circuit has found that, in some circumstances, the individual filing the motion does not need to comply with any of the requirements in *Matter of Lozada. See, e.g., Castillo-Perez* v. *INS*, 212 F.3d 518, 525–27 (9th Cir. 2000) (finding that there is no need to comply with *Matter of Lozada* where the record was undisputed that counsel failed, without any reason, to apply in a timely manner for relief for which the client was *prima facie* eligible while telling the client that he had filed for such relief); *Escobar-Grijalva*, 206 F.3d at 1335 (finding that there is no need to comply with *Matter of Lozada* where the record establishes on its face ineffective assistance of counsel). In *Tamang*, 598 F.3d at 1090, the Ninth Circuit distinguished prior cases in which "strict compliance with *Lozada* was not required because, under the circumstances of those cases, the ineffectiveness of counsel was plain on its face." The court found that, in Tamang's case, "without Tamang's compliance with the *Lozada* elements, . . . it is impossible to determine whether [his] ineffective assistance of counsel claim has merit." *Id.* Accordingly, the law with regard to compliance with the *Matter of Lozada* requirements varies significantly among the circuits.

The proposed rule would provide adjudicators with the discretion, committed exclusively to EOIR, to excuse noncompliance with the filing requirements in § 1003.48(b)(1)–(3) for compelling reasons in various limited circumstances. Collectively, the filing requirements at § 1003.48(b)(1)–(3) are designed to ensure that adjudicators have access to crucial information to help them determine whether an individual was subject to ineffective assistance of counsel and suffered prejudice. However, the Department recognizes that there are limited situations in which an individual is unable to comply with a filing requirement but can still demonstrate that he or she was subject to ineffective assistance of counsel and suffered prejudice as a result, such that it would be appropriate to grant his or her motion.

As noted above, § 1003.48(b)(1)(i) would provide that an individual filing a motion must submit an affidavit, or a written statement executed under the penalty of perjury as provided in 28 U.S.C. 1746, setting forth in detail the agreement that was entered into with respect to the actions to be taken by counsel and what representations counsel did or did not make in this regard. If the individual submits a written statement, § 1003.48(b)(1)(i) would permit the adjudicator, in an exercise of discretion committed exclusively to EOIR, to excuse the requirement that the written statement be executed under the penalty of perjury if there are compelling reasons why the written statement was not so executed and the motion is accompanied by certain other evidence. For example, if the individual is unrepresented and speaks little English, and submits a written statement that does not fully comply with the technical requirements of 28 U.S.C. 1746 for a document to be under the penalty of perjury, it may be appropriate for the adjudicator, in the exercise of discretion, to excuse for compelling reasons the requirement that the written statement be executed under the penalty of perjury. The Department expects that the waiver issue would arise almost exclusively in cases where the individual is unrepresented and is not familiar with the requirement to submit a written statement under the penalty of perjury, inasmuch as attorneys are familiar with requirements for the submission of affidavits and written statements under the penalty of perjury.

A waiver of the requirement that a written statement be executed under the penalty of perjury would be inappropriate in the absence of other evidence independently establishing that the individual was subject to ineffective assistance of counsel and suffered prejudice as a result. This approach is consistent with the general rule that assertions in a written statement that are not under the penalty of perjury would be entitled to little or no evidentiary weight. *Cf. Matter of S–M–*, 22 I&N Dec. 49, 51 (BIA 1998) (stating that "statements in a brief, motion, or Notice of Appeal are not evidence and thus are not entitled to any evidentiary weight").

The Department seeks comments from the public on this provision. First, the Department seeks comment on whether an individual should be required, without exception, to submit an affidavit or a written statement executed under the penalty of perjury, given that assertions in documents not under the penalty of perjury are generally given little or no evidentiary weight. If an exception should exist, the Department seeks comments on whether this exception should be formulated differently. For example, the Department has considered providing that the requirement that the written statement be executed under penalty of perjury could be excused if there is good cause to do so, or if exceptional circumstances are present. The Department seeks comments on whether either of these standards is more appropriate than the current proposed "compelling reasons" standard.

Similarly, the remaining requirements in proposed § 1003.48(b)(1)(ii)–(3), *i.e.*, submitting any representation agreement with counsel, providing notice to prior counsel, and filing a complaint with the appropriate disciplinary authorities, could be excused in limited instances for compelling reasons. An individual filing a motion would have the burden of establishing compelling reasons for excusing one of these requirements. A simple, unsupported, or blanket assertion of a difficulty or situation that inhibited compliance would not, on its own, suffice. Rather, the individual would have to explain the circumstances preventing his or her compliance, providing sufficient details and supporting documentation when appropriate. He or she should also provide other information to support his or her claim, such as explaining why the failure to comply could not or need not be remedied or producing alternative evidence. Ultimately, as each case would involve its own unique circumstances, the immigration judge and the Board would be in the best position to determine whether a filing requirement should be excused in a given case and whether the case warrants reopening in the exercise of discretion despite lack of compliance with regulatory requirements.

With respect to the requirement in § 1003.48(b)(1)(ii) that an individual filing a motion submit any applicable representation agreement with prior counsel, such an agreement is the best evidence of the nature, scope, or substance of the representation. However, if an individual filing a motion can establish compelling reasons for failing to submit such an agreement, then § 1003.48(b)(1)(ii) would permit the immigration judge or the Board, in the exercise of discretion committed exclusively to EOIR, to excuse this failure if the individual filing the motion submits other reasonably available evidence regarding his or her agreement with prior counsel.

With respect to the requirement in § 1003.48(b)(2) that an individual filing a motion notify prior counsel, the Department notes that State bar associations generally make their members' contact information publicly available. Further, the requirement to notify prior counsel applies even if a long period of time has passed since a person last had contact with the counsel. However, there are limited instances in which an individual filing a motion may be able to establish compelling reasons why he or she was unable to notify prior counsel. Examples may include instances where the prior counsel is incarcerated or has moved to a foreign country, or where the prior counsel is an individual the movant reasonably but erroneously believed to be an attorney or accredited representative and, despite diligent efforts, he or she cannot obtain prior counsel's contact information.

With respect to the requirement in § 1003.48(b)(3) that an individual filing a motion file a complaint with the appropriate disciplinary authorities, this standard is informed by the fact that the filing of a disciplinary complaint is "a relatively small inconvenience for an alien who asks that he or she be given a new hearing in a system that is already stretched in terms of its adjudicatory resources." *Matter of Rivera,* 21 I&N Dec. at 605. However, there are limited instances where an individual filing a motion may be able to establish compelling reasons for failing to file such a complaint. An example of such reasons may be the death of the counsel who allegedly provided the ineffective assistance. The Department notes that filing the complaint with the incorrect disciplinary authorities would not, on its own, excuse noncompliance with the filing requirement. If the individual files his or her complaint with the incorrect disciplinary authorities, he or she would have to re-file the complaint with the correct disciplinary authorities. The Department further notes that the fact that counsel has been disciplined, suspended from the practice of law, or disbarred would not, on its own, excuse an individual from filing the required disciplinary complaint. Even in the case of a disbarred attorney, complaints filed after disbarment may be relevant. In the majority of States, a disbarred attorney may seek readmission to the bar after a certain period of time. As such, in considering whether a disbarred attorney merits readmission, the licensing authority may consider complaints filed after disbarment.

It is important to consider the context for ineffective assistance of counsel claims under this rulemaking. These claims will typically arise after a final order has been entered in the case, and the proceedings have ended. The Department believes that the standards for excusing noncompliance with the filing requirements under § 1003.48(b)(1)–(3) must be carefully applied. In this regard, the adjudicator applying these standards should keep in mind the strong public and governmental interests in the expeditiousness and finality of proceedings. *See Abudu,* 485 U.S. at 107 (explaining that motions to reopen are disfavored because "[t]here is a strong public interest in bringing litigation to a close as promptly as is consistent with the interest in giving the adversaries a fair opportunity to develop and present their respective cases"). These interests dictate that a § 1003.48 filing requirement be excused sparingly and only in relatively few circumstances. The Department believes that the exceptions to the proposed rule's filing requirements are appropriately narrow, and that the requirements will accordingly be excused only rarely.

E. Standard in Proposed § 1003.48 for Evaluating Prejudice [9]

The proposed rule would provide that an individual who files a motion to reopen based upon a claim of ineffective assistance of counsel must establish that he or she was prejudiced by counsel's conduct. The Board and the courts of appeals have uniformly recognized that prejudice must be established in order to reopen removal, deportation, or exclusion proceedings based on a claim of ineffective assistance of counsel. *See, e.g., Matter of Lozada,* 19 I&N Dec. at 638; *Torres-Chavez* v. *Holder,* 567 F.3d 1096, 1100 (9th Cir. 2009); *Jiang,* 522 F.3d at 270; *Zeru* v. *Gonzales,* 503 F.3d 59, 72 (1st Cir. 2007); *Mai* v. *Gonzales,* 473 F.3d 162, 165 (5th Cir. 2006). The Board, however, has not established a standard for prejudice, and the courts of appeals, as set forth below, have provided varying standards.

This rule would set forth a single uniform standard for prejudice to be applied nationwide in ineffective assistance of counsel cases. This would ensure that individuals in similar situations would not be subject to disparate results based solely on the fact that their cases arose in different Federal jurisdictions. *See generally Matter of Cerna,* 20 I&N Dec. 399, 408 (BIA 1991) (explaining why immigration laws, to the "extent possible . . . should be applied in a uniform manner nationwide"), *superseded by regulation as stated in Martinez-Lopez* v. *Holder,* 704 F.3d 169, 172 (1st Cir. 2013); *Cazarez-Gutierrez* v. *Ashcroft,* 382 F.3d 905, 912 (9th Cir. 2004) (noting the "strong interest in national uniformity in the administration of immigration laws"); *Rosendo-Ramirez* v. *INS,* 32 F.3d 1085, 1091 (7th Cir. 1994) ("National uniformity in the immigration and naturalization laws is paramount: Rarely is the vision of a unitary nation so pronounced as in the laws that determine who may cross our national borders and who may become a citizen.").

As already noted, the lack of uniformity among the circuits is plain. The Sixth Circuit applies a very strict standard for evaluating prejudice in ineffective assistance of counsel immigration cases. *See, e.g., Sako,* 434 F.3d at 864 (holding that an individual "must establish that, but for the ineffective assistance of counsel, he would have been entitled to continue residing in the United States").

Several circuits apply a standard similar to that established by the Supreme Court in *Strickland* for ineffective assistance of counsel claims arising under the Sixth Amendment in criminal cases, which is a "reasonable probability that, but for counsel's unprofessional errors, the result of the proceeding would have been different." *Strickland,* 466 U.S. at 694. These include the Third and Eleventh Circuits. *See Rranci,* 540 F.3d at 175–76 ("a reasonable likelihood that the result would have been different if the error[s] . . . had not occurred") (brackets and ellipsis in original) (internal quotation marks omitted); *Dakane,* 399 F.3d at 1274 ("a reasonable probability that but for the attorney's error, the outcome of the proceedings would have been different'').[10]

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[9] The prejudice standard for motions to reopen *in absentia* proceedings based upon a claim of ineffective assistance of counsel is covered in section G discussed below.

At the other end of the spectrum, the Ninth Circuit deems the prejudice requirement satisfied so long as an individual can show ''plausible grounds for relief'' on the underlying claim. *See United States* v. *Barajas-Alvarado,* 655 F.3d 1077, 1089 (9th Cir. 2011) (stating that ''to show 'plausible grounds' for relief, an alien must show that, in light of the factors relevant to the form of relief being sought, and based on the 'unique circumstances of [the alien's] own case,' it was plausible (not merely conceivable) that the [immigration judge] would have exercised his discretion in the alien's favor'') (first brackets in original) (quoting *United States* v. *Corrales-Beltran,* 192 F.3d 1311, 1318 (9th Cir. 1999)); *Mohammed* v. *Gonzales,* 400 F.3d 785, 794 (9th Cir. 2005).

The Department has determined that using a prejudice standard modeled after *Strickland* would strike a proper balance between providing individuals with a reasonable opportunity to reopen proceedings based upon a meritorious ineffective assistance claim and safeguarding the finality of immigration proceedings. The proposed regulations would therefore provide that to succeed on an ineffective assistance of counsel claim, an individual needs to establish that ''there is a reasonable probability that, but for counsel's ineffective assistance, the result of the proceeding would have been different.'' [11] As mentioned above, several circuits have adopted this standard, which presents a middle ground among the standards adopted by the various circuits. Furthermore, as the Supreme Court has deemed a ''reasonable probability'' standard sufficient in the context of Sixth Amendment criminal cases, the Department considers the standard to be more than sufficient to use in the context of civil, administrative immigration proceedings.

Proposed § 1003.48(a)(3) would provide that eligibility for relief arising after proceedings have concluded ordinarily has no bearing on the prejudice determination. *Cf. Strickland,* 466 U.S. at 696 (stating that ''a court making the prejudice inquiry must ask if the defendant has met the burden of showing that the decision reached would reasonably likely have been different absent the errors''). There are exceptions to this general statement, however. For example, where a Form I–130, *Petition for Alien Relative,* has been filed with United States Citizenship and Immigration Services (USCIS) at DHS on behalf of an individual in removal proceedings, it may, in some instances, constitute ineffective assistance if counsel fails to request that the immigration judge continue the proceedings to await the adjudication of the petition. *Cf. Matter of Hashmi,* 24 I&N Dec. 785, 787–94 (BIA 2009) (articulating the factors for an immigration judge to consider in determining whether to continue removal proceedings pending USCIS's adjudication of an immigrant visa petition). If counsel acted ineffectively by failing to request a continuance, and the immigration judge ordered the individual removed but USCIS subsequently granted the petition, it would be appropriate to consider the individual's eligibility for adjustment of status in deciding whether he or she was prejudiced. That is, had the proceedings been continued, the result of the proceedings may have been different as the individual may have been able to apply for adjustment of status while they were ongoing. The Department seeks the public's comments on this issue, including on whether the reference to eligibility for relief arising after proceedings have concluded should be omitted from the final rule given the exception noted above.

The exact type of evidence that would suffice to establish a ''reasonable probability'' would be dependent upon the particular circumstances of a given case. The individual filing the motion would bear the burden, however, to show a reasonable probability that, but for counsel's ineffective assistance, the result of the proceeding would have been different. The individual filing the motion should submit any necessary evidence to establish prejudice, including affidavits or sworn statements from witnesses who were not previously called to testify or whose testimony was adversely impacted by the ineffectiveness of counsel, copies of vital documents that were not submitted in a timely manner, persuasive legal arguments that should have been included in missing or deficient briefs, missing applications for relief with supporting evidence, and any other evidence that serves to undermine the decision-maker's confidence in the outcome of the case. *See generally Strickland,* 466 U.S. at 694 (describing the manner in which the effect of alleged ineffective assistance of counsel on the reliability of a previous proceeding should be analyzed).

The Department notes that proposed § 1003.48 would provide two deviations from the ''reasonable probability'' standard. First, the rule would provide at § 1003.48(c)(3) that an individual is prejudiced by counsel's failure to file a petition for review with a Federal circuit court of appeals if he or she had ''plausible grounds for relief'' before the court. To establish that he or she was so prejudiced, the individual filing the motion must explain, with reasonable specificity, the ground or grounds for the petition. Neither the adjudicators nor opposing counsel should be expected to speculate as to what issues the individuals would have raised on appeal. The requirement that the ground or grounds for the petition for review must be explained ''with reasonable specificity'' would allow adjudicators to consider the filing party's sophistication in deciding whether prejudice has been established. In the Department's view, while some unrepresented individuals may explain the ground or grounds for appeal in general terms, attorneys and accredited representatives should explain, in detail, the factual and legal bases for appeal.

As discussed in section C of this preamble, for a motion based on counsel's failure to file a petition for review to be granted, the individual filing the motion would first have to establish that his or her prior counsel's conduct was ineffective within the scope of the counsel's representation. If the individual does not do so, the Board could deny the motion without addressing the issue of prejudice.

The second deviation from the ''reasonable probability'' standard is with respect to motions to reopen *in absentia* proceedings. As discussed in section G of this preamble, the rule would provide that an individual filing a motion is not required to establish proceedings.

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[10] The Eighth Circuit also used a similar standard before it found that there was no constitutionally-based right to effective counsel in removal proceedings. *See Obleshchenko,* 392 F.3d at 972; *see also Rafiyev,* 536 F.3d at 861 (concluding that there is no constitutional right under the Fifth Amendment to effective assistance of counsel in a removal proceeding). The Tenth Circuit has also employed this standard. *See, e.g., Delariva* v. *Holder,* 312 F. App'x 130, 132, 2009 WL 361373 (10th Cir. 2009) (unpublished) (citing *United States* v. *Aguirre-Tello,* 353 F.3d 1199, 1209 (10th Cir. 2004) (en banc)).

[11] This proposed rule would not provide that certain circumstances require a finding of *per se* prejudice. *See generally Matter of Assaad,* 23 I&N Dec. at 562 (rejecting the argument that the Board should apply a *per se* standard of prejudice to a counsel's failure to file an appeal in immigration proceedings); *cf. Siong* v. *INS,* 376 F.3d 1030, 1037 (9th Cir. 2004) (applying a rebuttable presumption of prejudice where counsel's error deprived an individual of any appeal in immigration proceedings). Rather, each case would rest on its own particulars, with the recognition that some conduct will more typically indicate prejudice, but that the individual filing the motion always carries the burden to establish that prejudice does in fact exist. As discussed in section G, however, an individual would not be required to establish prejudice in order to reopen *in absentia* proceedings.

F. Equitable Tolling and the Due Diligence Standard in Proposed § 1003.48

As discussed above, motions to reopen based upon a claim of ineffective assistance of counsel must be filed in accordance with the general requirements for motions provided in section 240(c)(7) of the Act and §§ 1003.2 and 1003.23 of the regulations. With a few exceptions noted in the regulations, motions to reopen must be filed within either 90 days or 180 days of the date of entry of a final administrative order of removal or deportation. In general, a motion to reopen must be filed within 90 days of the date of entry of a final order A motion to reopen proceedings to rescind an order of removal or deportation entered *in absentia* must be filed within 180 days of the order, however, if the motion alleges that the failure to appear was because of exceptional circumstances.

Every circuit court of appeals to have addressed the issue has recognized that equitable tolling may apply to untimely motions to reopen in some instances.[12] *See, e.g., Kuusk* v. *Holder,* 732 F.3d 302, 305 (4th Cir. 2013); *Avila-Santoyo* v. *U.S. Att'y Gen.*, 713 F.3d 1357, 1362–65 (11th Cir. 2013) (en banc) (per curiam); *Barry,* 524 F.3d at 724; *Yuan Gao* v. *Mukasey,* 519 F.3d 376, 377 (7th Cir. 2008); *Zhao* v. *INS,* 452 F.3d 154, 156–57 (2d Cir. 2006); *Mahmood* v. *Gonzales,* 427 F.3d 248, 251 (3d Cir. 2005); *Hernandez-Moran* v. *Gonzales,* 408 F.3d 496, 499–500 (8th Cir. 2005); *Riley* v. *INS,* 310 F.3d 1253, 1257–58 (10th Cir. 2002); *Socop-Gonzalez* v. *INS,* 272 F.3d 1176, 1187–93 (9th Cir. 2001) (en banc). However, as some of these courts have noted, "[e]quitable tolling is an extraordinary remedy which should be extended only sparingly[.]" *Mahmood,* 427 F.3d at 253 (first brackets in original) (internal quotation marks omitted); *see also Kuusk,* 732 F.3d at 306 (adhering "to the general principle that equitable tolling will be granted 'only sparingly,' not in 'a garden variety claim of excusable neglect' ") (quoting *Irwin* v. *Dep't of Veterans Affairs,* 498 U.S. 89, 96 (1990)); *Hernandez-Moran,* 408 F.3d at 499–500 (" '[E]quitable tolling is granted sparingly. Extraordinary circumstances far beyond the litigant's control must (brackets in original) (quoting *United States* v. *Marcello,* 212 F.3d 1005, 1010 (7th Cir. 2000)).

The First Circuit has not yet decided the applicability of equitable tolling to the filing deadlines for motions to reopen based upon ineffective assistance of counsel, but has assumed without deciding that tolling is available. *See Neves,* 613 F.3d at 36 (stating that "[w]e assume arguendo, but do not decide, that the time and number limits on motions to reopen are subject to equitable tolling"). The Fifth Circuit similarly has not decided this question. *See Reyes-Bonilla* v. *Lynch,* 616 F. App'x 193, 194 (5th Cir. 2015) (unpublished) (noting that "even if the immigration statutes are subject to equitable tolling, Reyes-Bonilla has failed to show that such tolling would apply").

In those circuits that have held that equitable tolling of the filing deadlines applies, the courts have differed on the precise standard for due diligence. The Board has not adopted a uniform approach to due diligence, instead applying the law of the circuit in which the motion was filed. *See, e.g., Yuan Gao,* 519 F.3d at 379. For example, the Ninth Circuit has found that the filing deadlines are equitably tolled "until the petitioner 'definitively learns' of counsel's fraud," although the petitioner must of course demonstrate that he or she exercised due diligence prior to this point as well. *Singh,* 491 F.3d at 1096 (citing *Albillo-DeLeon* v. *Gonzales,* 410 F.3d 1090, 1100 (9th Cir. 2005)); *see also Ghahremani* v. *Gonzales,* 498 F.3d 993, 999–1000 (9th Cir. 2007). The Second Circuit's due diligence analysis focuses on when the ineffective assistance "[was], or should have been, discovered by a reasonable person in the situation." *Iavorski* v. *INS,* 232 F.3d 124, 134 (2d Cir. 2000). The Seventh Circuit has stated that "'[e]quitable tolling requires a court to consider whether a reasonable person in the plaintiff's position would have been aware of the *possibility* that he had suffered' an injury." *Patel,* 442 F.3d at 1016 (quoting *Beamon* v. *Marshall & Ilsley Trust Co.,* 411 F.3d 854, 860–61 (7th Cir. 2005) (emphasis in original)). The Seventh Circuit has also held that when an individual learns of the ineffective assistance before the expiration of the statutory filing period and fails to explain why he or she was unable to file the motion within the statutory filing period, equitable tolling is not available and will not "reset the clock." *Yuan Gao,* 519 F.3d at 379 (finding that the individual filing the motion had "failed to point to any circumstances that made this the attempt to comply with the 90-day deadline would have failed, in which event an appeal to equitable tolling would lie"). The Ninth Circuit, by contrast, has held that equitable tolling may in fact have the effect of resetting the statute of limitations period. *See Socop-Gonzalez,* 272 F.3d at 1196 ("[W]e need only ask whether Socop filed within the limitations period after tolling is taken into account.").

With respect to the due diligence standard, some courts have emphasized that the individual filing the motion has a duty to investigate whether his or her counsel is ineffective. *See, e.g., Rashid* v. *Mukasey,* 533 F.3d 127, 132–133 n.3 (2d Cir. 2008) ("[A]n alien who is unfamiliar with the technicalities of immigration law can, under certain circumstances, be expected to comprehend that he has received ineffective assistance without being explicitly told so by an attorney . . . . Even someone not schooled in the technicalities of the law 'should have' recognized, under the[ ] circumstances [of this case], that his attorney was ineffective."); *see also Singh,* 491 F.3d at 1096–97 (finding that the individual filing the motion was not eligible for equitable tolling because he failed to investigate whether his attorney was ineffective).

There are also other considerations. Some circuits, such as the Second Circuit, have found that due diligence is required in both discovering the ineffectiveness and taking appropriate action upon discovery. *See, e.g., Rashid,* 533 F.3d at 132 (noting that "an alien is required to exercise due diligence both before *and* after he has or should have discovered ineffective assistance of counsel") (emphasis in original); *see also Wang* v. *Board of Immigration Appeals,* 508 F.3d 710, 715 (2d Cir. 2007) (noting that an individual filing a motion "bears the burden of proving that he has exercised due diligence in the period between discovering the ineffectiveness of his representation and filing the motion to reopen"). Other courts have similarly required that the motion to reopen must be filed within a reasonable time of discovering the ineffective assistance. *See, e.g., Tapia-Martinez* v. *Gonzales,* 482 F.3d 417, 423–24 (6th Cir. 2007) (finding that the individual filing the motion did not exercise due diligence because she filed the motion to reopen more than fifteen months after discovering her prior counsel's ineffectiveness); *see also Pafe* v. *Holder,* 615 F.3d 967, 969 (8th Cir. 2010) (finding that, despite existence of fraud and deception by prior attorneys, the Board did not abuse its discretion in the individual waited nearly six years to file the motion); *Jobe* v. *INS,* 238 F.3d 96, 100–01 (1st Cir. 2001) (en banc) (declining to find due diligence where an individual waited to file a motion to reopen to rescind an *in absentia* order more than half a year after he "learned that an [immigration judge] had taken some action on his asylum application and was advised to consult an attorney immediately").

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[12] As noted above, equitable tolling refers to "[t]he doctrine that the statute of limitations will not bar a claim if the plaintiff, despite diligent efforts, did not discover the injury until after the limitations period had expired." *Black's Law Dictionary* 579 (8th ed. 2004).

The Department has determined that it may be appropriate in certain circumstances for an immigration judge or the Board to equitably toll the filing deadlines in section 240(c)(7) of the Act and §§ 1003.2 and 1003.23 of the regulations where the basis of the motion is a claim of ineffective assistance of counsel.[13] Accordingly, the proposed rule would provide, at § 1003.48(d), that these filing deadlines shall be tolled if a motion to reopen is based upon a claim of ineffective assistance of counsel, the ineffective assistance prevented the timely filing of the motion, and the individual filing the motion exercised due diligence in discovering the ineffective assistance. Specifically, the proposed rule would provide that, if an individual exercised due diligence in discovering the ineffective assistance, he or she has 90 days after discovering the ineffective assistance to file the motion to reopen. This 90-day filing period would apply to all motions to reopen based on ineffective assistance of counsel, including motions to reopen to rescind an *in absentia* order based on exceptional circumstances arising from a claim of ineffective assistance of diligence if he or she discovers the ineffective assistance within the time it should have been discovered by a reasonable person in his or her position. The Department notes that equitable tolling would not shorten the filing deadlines set out in §§ 1003.2 and 1003.23.

The Department recognizes that some motions to rescind *in absentia* orders and reopen proceedings are not subject to time limitations. *See, e.g., Matter of Bulnes,* 25 I&N Dec. 57, 59 (BIA 2009) (motions to reopen to rescind *in absentia* orders where the individual demonstrates he or she did not receive notice); *Matter of Cruz-Garcia,* 22 I&N Dec. 1155, 1157–59 (BIA 1999) (deportation proceedings under former section 242(b) of the Act); *Matter of N–B–,* 22 I&N Dec. 590, 591–93 (BIA 1999) (exclusion proceedings). We are soliciting comments on whether the requirements of this new rule should be applied to motions to reopen filed in such cases on the basis of a claim of ineffective assistance of counsel.

As discussed above, there is variation among the courts of appeals regarding the exact standard for determining that an individual exercised due diligence in discovering ineffective assistance of counsel. While eligibility for equitable tolling will depend upon the particulars of the case, the Department seeks to promote uniformity in the due diligence standard. As such, the Department considered various standards of the courts of appeals for evaluating due diligence. For example, the Department considered standards requiring the immigration judge or the Board to determine when the individual filing the motion, acting with due diligence, definitively learned of the ineffective assistance of counsel,[14] or to evaluate when a reasonable person in that individual's position would have been aware of the possibility that he or she had been prejudiced by counsel's conduct.[15] After review of the case law discussed above, the Department is proposing to include a standard for evaluating due diligence that would require the immigration judge or the Board to determine when the ineffective assistance should have been discovered by a reasonable person in the individual's position. This standard is consistent with the Second Circuit's case law discussed above,[16] as well as the "discovery rule" used in certain non-immigration cases to determine

The evidence required for demonstrating due diligence would vary from case to case. However, to establish due diligence, an individual would ordinarily have to present evidence that he or she timely inquired about his or her immigration status and the progress of his or her case.

The Department welcomes comments from the public on the appropriateness of including the remedy of equitable tolling and the proposed standard for assessing due diligence in the rule.

G. Effect of Proposed § 1003.48 on Motions To Reopen and To Rescind an Order of Removal, Deportation, or Exclusion Entered in Absentia

The proposed rule would add a cross-reference to new § 1003.48 in the regulations governing motions to reopen proceedings and rescind orders of removal, deportation, or exclusion entered *in absentia.* An order of removal entered *in absentia* in removal proceedings pursuant to section 240(b)(5) of the Act may be rescinded upon a motion to reopen filed within 180 days after the date of the order, if the individual filing the motion demonstrates that the failure to appear was because of exceptional circumstances as defined in section 240(e)(1) of the Act. An order of exclusion entered *in absentia* may be rescinded upon a motion to reopen filed at any time if the individual demonstrates reasonable cause for his or her failure to appear. The standard for rescinding orders of deportation entered *in absentia* varies. Orders subject to section 240(b)(5) of the Act may be rescinded upon a motion filed within 180 days of the order if the individual demonstrates that the failure to appear was because of exceptional circumstances beyond his or her control.[18] Orders subject to a provision of the INA in effect before June 13, 1992, may be rescinded upon a motion filed at any time if the individual demonstrates reasonable cause for his or her failure to appear. *See Matter of Cruz-Garcia,* 22 I&N Dec. at 1157–59.

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[13] The Department notes that there are other regulations governing special motions to reopen for suspension of deportation and cancellation of removal pursuant to section 203(c) of the Nicaraguan Adjustment and Central American Relief Act (NACARA) (Pub. L. 105–100, tit. II) and section 1505(c) of the LIFE Act Amendments of 2000 (Pub. L. 106–554, tit. XV). *See* 8 CFR 1003.43. In addition, there are regulations governing special motions to seek relief under former section 212(c) of the Act. *See* 8 CFR 1003.44. The Department notes that there may be circuit law addressing the applicability of equitable tolling to the filing deadlines of these special motions to reopen. *See, e.g., Albillo-De Leon,* 410 F.3d at 1098 (finding that section 203(c) of NACARA is subject to equitable tolling); *Johnson* v. *Gonzales,* 478 F.3d 795, 799 (7th Cir. 2007) (declining, for lack of due diligence, to equitably toll the deadline for filing a motion to reopen to apply for relief under former section 212(c) of the Act). This proposed rule would not address whether ineffective assistance of counsel may be a basis to toll the filing deadlines of these special motions. The Department welcomes comment from the public regarding whether ineffective assistance of counsel should be a basis for tolling the filing deadlines of these special motions and whether the proposed rule should be expanded to cover those situations.

[14] *See Singh,* 491 F.3d at 1096.

[15] *See Patel,* 442 F.3d at 1016.

[16] *See Iavorski,* 232 F.3d at 134.

[17] Depending upon the type of case, jurisdiction, and applicable exceptions, the "discovery rule" permits an individual to file a suit in a civil case within a certain period of time after the injury is discovered, or reasonably should have been discovered. *See, e.g., Black's Law Dictionary* 499 (8th ed. 2004) (defining the discovery rule as "[t]he rule that a limitations period does not begin to run until the plaintiff discovers (or reasonably should have discovered) the injury giving rise to the claim").

[18] In addition, removal and deportation orders entered *in absentia* may be rescinded upon a motion filed at any time when the individual filing the motion demonstrates that he or she did not receive the requisite notice, or that he or she was in Federal or State custody and the failure to appear was through no fault of the individual. *See* INA 240(b)(5)(C)(ii).

As has been established in Board precedent, this rule would provide that an individual may establish exceptional circumstances or reasonable cause, whichever is applicable, by demonstrating that the failure to appear was due to ineffective assistance of counsel. *See Matter of Grijalva,* 21 I&N Dec. 472, 473–74 (BIA 1996); *see also Matter of Rivera,* 21 I&N Dec. at 602. In establishing exceptional circumstances or reasonable cause based upon ineffective assistance of counsel, an individual would generally have to comply with the requirements for motions provided in new § 1003.48. However, consistent with the Board's longstanding practice, that individual would not be required to establish that he or she was prejudiced. *See Matter of Grijalva,* 21 I&N Dec. at 473 n.2; *see also Matter of Rivera,* 21 I&N Dec. at 603 n.1.

As discussed above, the rule would also permit equitable tolling of the time limitations on filing of motions to reopen and rescind an *in absentia* order. Provided that the individual establishes that he or she exercised due diligence in discovering his or her counsel's ineffectiveness, the individual would have 90 days from when the ineffective assistance was discovered to file a motion to reopen and rescind an *in absentia* order.[19] The Department notes that equitable tolling does not shorten the filing deadlines set out in §§ 1003.2 and 1003.23.

IV. Ineffective Assistance of Counsel and the Asylum One-Year Filing Deadline

The Department and DHS have independent roles and authorities with respect to the adjudication of applications for asylum under section 208 of the Act. As a general matter, DHS asylum officers have authority to adjudicate affirmative asylum applications filed with USCIS, while the immigration judges in EOIR have authority to adjudicate the asylum applications of individuals who are the subject of proceedings before EOIR. Under section 208(a)(2)(D) of the Act, an application for asylum may be considered despite the fact that it was not filed within one year of the applicant's arrival in the United States where he or she establishes "extraordinary circumstances" relating to the delay in filing of the application. The regulations of EOIR and DHS provide a non-exclusive list of situations that could fall within the extraordinary circumstances definition and specifically provide that a claim of ineffective assistance of counsel may constitute extraordinary circumstances excusing an applicant's failure to timely file an application for asylum. *See* 8 CFR 208.4(a)(5)(iii), 1208.4(a)(5)(iii).

This rule proposes to amend the EOIR asylum regulations at 8 CFR 1208.4(a)(5) to incorporate some of the language used in the motion to reopen provisions in proposed § 1003.48 for extraordinary circumstances claims based upon a claim of ineffective assistance of counsel. The provisions of the rule addressing the one-year deadline for filing for asylum will apply upon the effective date of the final rule.

The Department notes that this rule proposes to amend only the EOIR asylum regulations in 8 CFR 1208.4.

V. Regulatory Requirements

A. Regulatory Flexibility Act

The Department has reviewed this regulation in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)) and has determined that this rule will not have a significant economic impact on a substantial number of small entities. The rule will not regulate "small entities," as that term is defined in 5 U.S.C. 601(6).

B. Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

C. Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996. 5 U.S.C. 804. This rule will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

D. Executive Orders 12866 and 13563

The proposed rule is considered by the Department to be a "significant regulatory action" under section 3(f)(4) of Executive Order 12866. Accordingly, the regulation has been submitted to the Office of Management and Budget (OMB) for review. The Department certifies that this regulation has been drafted in accordance with the principles of Executive Order 12866, section 1(b), and Executive Order 13563. Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of using the best available methods to quantify costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

The Department believes that this proposed rule would provide significant net benefits relating to EOIR proceedings. *See* Executive Order 12866(b)(6) (stating that "[e]ach agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs"). The proposed rule would help ensure the fairness and integrity of these proceedings by setting out a standard set of requirements for reopening proceedings, allowing for reopening where an individual was genuinely subjected to ineffective assistance of counsel and suffered prejudice as a result. The Department is unaware of any monetary costs on public entities that the rule would impose. Further, the Department does not believe that, broadly speaking, the proposed rule could be said to burden the parties in EOIR proceedings, as the rule simply changes an adjudicatory standard used in those proceedings, generally striking a middle ground between the circuit courts' approaches.[20]

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[19] *But see supra* note 13.

[20] For example, as noted above, the proposed rule's standard for establishing prejudice would be more lenient than the Sixth Circuit's current standard but stricter than the Ninth Circuit's. The proposed rule would provide at § 1003.48(a)(3) that, for an individual to establish that he or she was prejudiced by counsel's ineffective assistance, the individual must show that "there is a reasonable probability that, but for counsel's ineffective assistance, the result of the proceeding would have been different." Currently, the Sixth Circuit requires an individual to "establish that, but for the ineffective assistance of counsel, he would have been entitled to continue residing in the United States." *Sako,* 434 F.3d at 864. However, the Ninth Circuit simply requires an individual to show that

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E. Executive Order 13132: Federalism

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

F. Executive Order 12988: Civil Justice Reform

This rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

G. Paperwork Reduction Act

This rule does not propose new or revisions to existing "collection[s] of information" as that term is defined under the Paperwork Reduction Act of 1995, Public Law 104–13, 44 U.S.C. chapter 35, and its implementing regulations, 5 CFR part 1320.

List of Subjects

8 CFR Part 1003

Administrative practice and procedure, Aliens, Immigration.

8 CFR Part 1208

Administrative practice and procedure, Aliens, Immigration.

Accordingly, for the reasons set forth in the preamble, the Attorney General is proposing to amend title 8, chapter V of the Code of Federal Regulations as follows:

PART 1003—EXECUTIVE OFFICE FOR IMMIGRATION REVIEW

■ 1. The authority for part 1003 continues to read as follows:

Authority: 5 U.S.C. 301, 6 U.S.C. 521; 8 U.S.C. 1101, 1103, 1154, 1155, 1158, 1182, 1226, 1229, 1229a, 1229b, 1229c, 1231, 1254a, 1255, 1324d, 1330, 1361, 1362; 28 U.S.C. 509, 510, 1746; sec. 2 Reorg. Plan No. 2 of 1950; 3 CFR, 1949–1953, Comp., p. 1002; section 203 of Pub. L. 105–100, 111 Stat. 2196–200; sections 1506 and 1510 of Pub. L. 106–386, 114 Stat. 1527–29, 1531–32; section 1505 of Pub. L. 106–554, 114 Stat. 2763A–326 to –328.

■ 2. Section 1003.23 is amended by adding a new paragraph (b)(4)(v), to read as follows:

§ 1003.23 Reopening or reconsideration before the Immigration Court.

* * * * *

(b) * * *

(4) * * *

(v) *Motions to reopen and rescind an in absentia order based upon a claim of ineffective assistance of counsel.* A motion to reopen proceedings and rescind an in absentia order of removal, deportation, or exclusion is subject to the requirements for such motions under paragraph (b)(4)(ii) or (b)(4)(iii)(A) of this section and § 1003.48. For a motion to reopen proceedings and rescind an in absentia order of removal, deportation, or exclusion, the alien may establish exceptional circumstances or other appropriate legal standards to reopen proceedings based upon a claim of ineffective assistance of counsel. The alien does not need to establish prejudice in order to reopen proceedings and rescind an order of removal, deportation, or exclusion entered in absentia based upon a claim of ineffective assistance of counsel. Deadlines for motions to reopen and rescind an in absentia order based upon a claim of ineffective assistance of counsel may be equitably tolled pursuant to § 1003.48(d). The term "counsel," as used in this subsection, only applies to the conduct of an attorney or an accredited representative as defined in part 1292, or a person whom the alien reasonably but erroneously believed to be an attorney or an accredited representative and who was retained to represent the alien in proceedings.

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■ 3. Add § 1003.48 to subpart A to read as follows:

§ 1003.48 Reopening based upon a claim of ineffective assistance of counsel.

(a) *Standard for adjudication.* Except as provided in this section, a motion to reopen proceedings before the Board or an immigration judge based upon a claim of ineffective assistance of counsel will be adjudicated in accordance with section 240(c)(7) of the Act and the applicable regulations governing motions at §§ 1003.2 and 1003.23. The individual filing the motion must demonstrate that counsel's conduct was ineffective and prejudiced the individual.

(1) *Conduct covered.* Except as provided in paragraph (c) of this section, this section covers conduct that occurred while removal, deportation, or exclusion proceedings were pending before the Board or an immigration judge. The term "counsel," as used in this section, only applies to the conduct of:

(i) An attorney or an accredited representative as defined in part 1292; or

(ii) A person whom the individual filing the motion reasonably but erroneously believed to be an attorney or an accredited representative and who was retained to represent him or her in the proceedings before the Board or an immigration judge.

(2) *Standard for evaluating counsel's ineffectiveness.* A counsel's conduct constitutes ineffective assistance of counsel if the conduct was unreasonable, based on the facts of the particular case, viewed as of the time of the conduct.

(3) *Standard for evaluating prejudice.* Except as provided in paragraph (c)(3) of this section, in evaluating whether an individual has established that he or she was prejudiced by counsel's conduct, the Board or the immigration judge shall determine whether there is a reasonable probability that, but for counsel's ineffective assistance, the result of the proceeding would have been different. Eligibility for relief occurring after the conclusion of proceedings will ordinarily have no bearing on the determination of whether the individual was prejudiced during the course of proceedings.

(b) *Form, contents, and procedure for filing a motion to reopen based upon a claim of ineffective assistance of counsel.* A motion to reopen under this section must be filed in accordance with section 240(c)(7) of the Act or other applicable statutory provisions, and the applicable regulations at §§ 1003.2 and 1003.23 governing motions to reopen. The motion must include the following items to support the claim of ineffective assistance of counsel:

(1) *Affidavit or written statement.* (i) The individual filing the motion must, in every case, submit an affidavit, or a written statement executed under the penalty of perjury as provided in 28 U.S.C. 1746, setting forth in detail the agreement that was entered into with counsel with respect to the actions to be taken by counsel and what representations counsel did or did not make to the individual in this regard. If the individual submits a written statement not executed under the penalty of perjury, the Board or the immigration judge may, in an exercise of discretion committed exclusively to the agency, excuse the requirement that the written statement must be executed under the penalty of perjury, if:

(A) There are compelling reasons why the written statement was not executed under the penalty of perjury; and

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he or she "had plausible grounds for . . . relief." *Barajas-Alvarado*, 655 F.3d at 1089 (quotation omitted).

(B) The motion is accompanied by other evidence independently establishing that the individual was subject to ineffective assistance of counsel and suffered prejudice as a result.

(ii) In addition, the individual filing the motion must submit a copy of any applicable representation agreement in support of the affidavit or written statement. If no representation agreement is provided, the individual must explain its absence in the affidavit or written statement and provide any reasonably available evidence on the scope of the agreement and the reason for its absence. The Board or an immigration judge may, in an exercise of discretion committed exclusively to the agency, excuse failure to provide any applicable representation agreement in support of the affidavit or written statement if the individual establishes that there are compelling reasons for the failure to provide the representation agreement and he or she presents other reasonably available evidence regarding the agreement made with counsel.

(2) *Notice to counsel.* The individual filing the motion must provide evidence that he or she informed counsel whose representation is claimed to have been ineffective of the allegations leveled against that counsel and that a motion to reopen alleging ineffective assistance of counsel will be filed on that basis. The individual must provide evidence of the date and manner in which he or she provided notice to prior counsel and include a copy of the correspondence sent to the prior counsel and the response from the prior counsel, if any, or state that no such response was received. The requirement that the individual provide a copy of any response from prior counsel continues until such time as a decision is rendered on the motion to reopen. The Board or an immigration judge may, in an exercise of discretion committed exclusively to the agency, excuse failure to provide the required notice if the individual establishes that there are compelling reasons why he or she was unable to notify the prior counsel.

(3) *Complaint filed with the appropriate disciplinary authorities.* The individual filing the motion must file a complaint with the appropriate disciplinary authorities with respect to any violation of counsel's ethical or legal responsibilities, and provide a copy of that complaint and any correspondence from such authorities. The Board or an immigration judge may, in an exercise of discretion committed exclusively to the agency, excuse the failure to file a complaint if the individual establishes that there are compelling reasons why he or she was unable to notify the appropriate disciplinary authorities. The fact that counsel has already been disciplined, suspended from the practice of law, or disbarred does not, on its own, excuse the individual from filing the required disciplinary complaint. The appropriate disciplinary authorities are as follows:

(i) With respect to attorneys in the United States: The licensing authority of a state, possession, territory, or Commonwealth of the United States, or of the District of Columbia that has licensed the attorney to practice law.

(ii) With respect to accredited representatives: The EOIR disciplinary counsel pursuant to § 1003.104(a).

(iii) With respect to a person whom the individual reasonably but erroneously believed to be an attorney or an accredited representative and who was retained to represent him or her in proceedings: The appropriate Federal, State, or local law enforcement agency with authority over matters relating to the unauthorized practice of law or immigration-related fraud.

(4) *Prejudice.* Except as provided in § 1003.23(b)(4)(v), the individual filing the motion shall establish that he or she was prejudiced by counsel's conduct. The standard for prejudice is set forth in paragraph (a)(3) of this section, except as provided in paragraph (c)(3) of this section. The Board or an immigration judge shall not waive the requirement to establish prejudice.

(c) *Claims of ineffective assistance of counsel based upon conduct occurring after entry of a final order of removal, deportation, or exclusion.* (1) *Scope of review.* After entry of a final order of removal, deportation, or exclusion, the Board has discretion pursuant to §§ 1003.2 and 1003.48 to reopen removal, deportation, or exclusion proceedings based upon counsel's failure to file a timely petition for review in the Federal court of appeals. Such discretion, however, shall not extend to other claims based upon counsel's conduct before another administrative or judicial body. Except as described in paragraph (c)(3) of this section, a motion to reopen based upon counsel's failure to file a timely petition for review in the Federal court of appeals must meet the requirements set forth in paragraph (b) of this section.

(2) *Establishing ineffective assistance.* To establish that counsel provided ineffective assistance, an individual seeking to reopen removal, deportation, or exclusion proceedings based upon counsel's failure to file a timely petition for review in the Federal court of appeals must establish that counsel had agreed to file a petition for review but failed to do so. For the individual to meet this burden, he or she must submit a representation agreement making clear that the scope of counsel's representation included the filing of a petition for review, or must otherwise establish that the scope of the representation included the filing of a petition for review.

(3) *Establishing prejudice.* An individual is prejudiced by counsel's failure to file a petition for review with a Federal circuit court of appeals if he or she had plausible ground for relief before the court. To establish that he or she was so prejudiced, the individual filing the motion must explain, with reasonable specificity, the ground or grounds for the petition.

(d) *Due diligence and equitable tolling.* (1) The time limitations set forth in §§ 1003.2 and 1003.23 shall be tolled if:

(i) The motion to reopen is based upon a claim of ineffective assistance of counsel;

(ii) The individual filing the motion has established that he or she exercised due diligence in discovering the ineffective assistance of counsel; and

(iii) The motion is filed within 90 days after the individual discovered the ineffective assistance of counsel.

(2) In evaluating whether an individual has established that he or she has exercised due diligence, the standard is when the ineffective assistance should have been discovered by a reasonable person in the individual's position.

(e) *Applicability date.* This section applies only to motions filed on or after [effective date of final rule].

* * * * *

PART 1208—PROCEDURES FOR ASYLUM AND WITHHOLDING OF REMOVAL

■ 4. The authority for part 1208 continues to read as follows:

Authority: 8 U.S.C. 1103, 1158, 1225, 1231, 1282.

■ 5. Section 1208.4 is amended by revising paragraphs (a)(5)(iii)(A), (B), and (C) and adding paragraph (a)(5)(iii)(D) to read as follows:

§ 1208.4 Filing the application.

* * * * *

(a) * * *

(5) * * *

(iii) * * *

(A) The applicant files an affidavit, or a written statement executed under the penalty of perjury as provided in 28 U.S.C. 1746, setting forth in detail the agreement that was entered into with counsel with respect to the actions to be taken by counsel and what representations counsel did or did not make to the applicant in this regard. If the applicant submits a written statement not executed under the penalty of perjury, the Board or the immigration judge may, in an exercise of discretion committed exclusively to the agency, excuse the requirement that the written statement must be executed under the penalty of perjury, if there are compelling reasons why the written statement was not executed under the penalty of perjury, and the applicant submits other evidence establishing that he or she was subject to ineffective assistance of counsel and suffered prejudice as a result. In addition, in all cases, the applicant must either submit a copy of any applicable representation agreement in support of the affidavit or written statement or explain its absence in the affidavit or written statement. Failure to provide any applicable representation agreement in support of the affidavit or written statement may be excused, in an exercise of discretion committed exclusively to the agency, if the applicant establishes that there are compelling reasons that he or she was unable to provide any representation agreement.

(B) The applicant provides evidence that he or she informed counsel whose representation is claimed to have been ineffective of the allegations leveled against him or her. The applicant must provide evidence of the date and manner in which he or she provided notice to his or her prior counsel; and include a copy of the correspondence sent to the prior counsel and the response from the prior counsel, if any, or state that no such response was received. Failure to provide the required notice to counsel may be excused, in an exercise of discretion committed exclusively to the agency, if the applicant establishes that there are compelling reasons why he or she was unable to notify counsel.

(C) The applicant files and provides a copy of the complaint filed with the appropriate disciplinary authorities with respect to any violation of counsel's ethical or legal responsibilities, and any correspondence from such authorities. Failure to provide the complaint may be excused, in an exercise of discretion committed exclusively to the agency, if the applicant establishes that there were compelling reasons why he or she was unable to notify the appropriate disciplinary authorities. The fact that counsel has already been disciplined, suspended from the practice of law, or disbarred does not, on its own, excuse the applicant from filing the required disciplinary complaint. The appropriate disciplinary authorities are as follows:

(*1*) With respect to attorneys in the United States: The licensing authority of a State, possession, territory, or Commonwealth of the United States, or of the District of Columbia that has licensed the attorney to practice law.

(*2*) With respect to accredited representatives: The EOIR disciplinary counsel pursuant to § 1003.104(a).

(*3*) With respect to a person whom the applicant reasonably but erroneously believed to be an attorney or an accredited representative and who was retained to represent him or her in proceedings before the immigration courts and the Board: The appropriate Federal, State or local law enforcement agency with authority over matters relating to the unauthorized practice of law or immigration-related fraud.

(D) The term "counsel," as used in this paragraph (a)(5)(iii), only applies to the conduct of an attorney or an accredited representative as defined in part 1292 of this chapter, or a person whom the applicant reasonably but erroneously believed to be an attorney or an accredited representative and who was retained to represent him or her in proceedings before the immigration courts and the Board.

* * * * *

Dated: July 19, 2016.

Loretta Lynch,

Attorney General.

[FR Doc. 2016–17540 Filed 7–27–16; 8:45 am]

BILLING CODE 4410–30–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–8181; Directorate Identifier 2016–NM–002–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain The Boeing Company Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747–400, 747–400D, 747–400F, 747SR, and 747SP series airplanes. This proposed AD was prompted by an evaluation by the design approval holder (DAH) indicating that the nose wheel well is subject to widespread fatigue damage (WFD). This proposed AD would require modification of the nose wheel body structure; a detailed inspection of the nose wheel body structure for any cracking; a surface high frequency eddy current inspection (HFEC) or an open hole HFEC inspection of the vertical beam outer chord and web for any cracking; and all applicable related investigative actions including repetitive inspections, and other specified and corrective actions. We are proposing this AD to detect and correct fatigue cracking in the nose wheel well structure; such cracking could adversely affect the structural integrity of the airplane.

DATES: We must receive comments on this proposed AD by September 12, 2016.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com*. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8181.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. 2016–8181; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Nathan Weigand, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6428; fax: 425–917–6590; email: *Nathan.P.Weigand@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. 2016–8181; Directorate Identifier 2016–NM–002–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

Fatigue damage can occur locally, in small areas or structural design details, or globally, in widespread areas. Multiple-site damage is widespread damage that occurs in a large structural element such as a single rivet line of a lap splice joining two large skin panels. Widespread damage can also occur in multiple elements such as adjacent frames or stringers. Multiple-site damage and multiple-element damage cracks are typically too small initially to be reliably detected with normal inspection methods. Without intervention, these cracks will grow, and eventually compromise the structural integrity of the airplane. This condition is known as widespread fatigue damage. It is associated with general degradation of large areas of structure with similar structural details and stress levels. As an airplane ages, WFD will likely occur, and will certainly occur if the airplane is operated long enough without any intervention.

The FAA's WFD final rule (75 FR 69746, November 15, 2010) became effective on January 14, 2011. The WFD rule requires certain actions to prevent structural failure due to WFD throughout the operational life of certain existing transport category airplanes and all of these airplanes that will be certificated in the future. For existing and future airplanes subject to the WFD rule, the rule requires that DAHs establish a limit of validity (LOV) of the engineering data that support the structural maintenance program. Operators affected by the WFD rule may not fly an airplane beyond its LOV, unless an extended LOV is approved.

The WFD rule (75 FR 69746, November 15, 2010) does not require identifying and developing maintenance actions if the DAHs can show that such actions are not necessary to prevent WFD before the airplane reaches the LOV. Many LOVs, however, do depend on accomplishment of future maintenance actions. As stated in the WFD rule, any maintenance actions necessary to reach the LOV will be mandated by airworthiness directives through separate rulemaking actions.

In the context of WFD, this action is necessary to enable DAHs to propose LOVs that allow operators the longest operational lives for their airplanes, and still ensure that WFD will not occur. This approach allows for an implementation strategy that provides flexibility to DAHs in determining the timing of service information development (with FAA approval), while providing operators with certainty regarding the LOV applicable to their airplanes.

We received an evaluation by the DAH indicating that the nose wheel well is subject to WFD. This condition, if not corrected, could result in cracking in the nose wheel well structure; such cracking could adversely affect the structural integrity of the airplane.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Alert Service Bulletin 747–53A2887, dated December 2, 2015. The service information describes procedures for modification of the nose wheel body structure; a detailed inspection of the nose wheel body structure for any cracking; a web surface HFEC and an open hole HFEC inspection of the vertical beam outer chord for any cracking; and repair. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in the service information described previously, except as discussed under "Differences Between this Proposed AD and the Service Information."

Differences Between This Proposed AD and the Service Information

Boeing Alert Service Bulletin 747–53A2887, dated December 2, 2015, specifies to contact the manufacturer for certain instructions, but this AD requires accomplishment of repair methods, modification deviations, and alteration deviations in one of the following ways:

- In accordance with a method that we approve; or
- Using data that meet the certification basis of the airplane, and that have been approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) whom we have authorized to make those findings.

Explanation of Compliance Time

The compliance time for the modification specified in this proposed AD for addressing WFD was established to ensure that discrepant structure is modified before WFD develops in airplanes. Standard inspection techniques cannot be relied on to detect WFD before it becomes a hazard to flight. We will not grant any extensions of the compliance time to complete any AD-mandated service bulletin related to WFD without extensive new data that would substantiate and clearly warrant such an extension.

Costs of Compliance

We estimate that this proposed AD affects 107 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Modification	408 work-hours × $85 per hour = $34,680.	$15,743	$50,423	$5,395,261.
Part 2 detailed inspection	140 work-hours × $85 per hour = $11,900 per inspection cycle.	0	$11,900 per inspection cycle	$1,273,300 per inspection cycle.
Surface HFEC inspection	4 work-hours × $85 per hour = $340 per inspection cycle.	0	$340 per inspection cycle	Up to $36,380 per inspection cycle.
Open hole HFEC inspection	4 work-hours × $85 per hour = $340 per inspection cycle.	0	$340 per inspection cycle	Up to $36,380 per inspection cycle.

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this proposed AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a "significant regulatory action" under Executive Order 12866,

(2) Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

The Boeing Company: Docket No. 2016–8181; Directorate Identifier 2016–NM–002–AD.

(a) Comments Due Date

We must receive comments by September 12, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747–400, 747–400D, 747–400F, 747SR, and 747SP series airplanes, certificated in any category, identified in Boeing Alert Service Bulletin 747–53A2887, dated December 2, 2015.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by an evaluation by the design approval holder indicating that the nose wheel well is subject to widespread fatigue damage. We are issuing this AD to detect and correct fatigue cracking in the nose wheel well structure; such cracking could adversely affect the structural integrity of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Modification for Groups 1 and 4 Airplanes

For groups 1 and 4 airplanes as identified in Boeing Alert Service Bulletin 747–53A2887, dated December 2, 2015: Except as required by paragraph (j)(1) of this AD, at the applicable time specified in paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 747–53A2887, dated December 2, 2015, modify the nose wheel body structure, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 747–53A2887, dated December 2, 2015.

(h) Inspection for Groups 1 and 4 Airplanes

For groups 1 and 4 airplanes on which the actions of paragraph (g) have been done: Except as required by paragraph (j)(1) of this AD, at the applicable time specified in paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 747–53A2887, dated December 2, 2015, do a detailed inspection of the nose wheel body structure for any cracking; do a surface high frequency eddy current inspection (HFEC) or an open hole HFEC inspection of the vertical beam outer chord and web for any cracking; and do all applicable related investigative, other specified actions, and corrective actions, in accordance with the Accomplishment Instruction of Boeing Alert Service Bulletin 747–53A2887, dated December 2, 2015; except as required by paragraph (j)(2) of this AD. Do all applicable related investigative actions, other specified actions, and corrective actions before further flight. Repeat the detailed inspection of the nose wheel body structure, and either the surface HFEC or the open hole HFEC inspection of the vertical beam outer chord, thereafter, at the applicable interval specified in paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 747–53A2887, dated December 2, 2015.

(i) Inspection for Groups 2, 3, 5 and 6 Airplanes

For groups 2, 3, 5 and 6 airplanes identified in Boeing Alert Service Bulletin 747–53A2887, dated December 2, 2015: Except as required by paragraph (j)(1) of this AD, at the applicable time specified in paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 747–53A2887, dated December 2, 2015, do a detailed inspection of the nose wheel well body structure for any cracking, and do all applicable related investigative and corrective actions, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 747–53A2887, dated December 2, 2015; except as required by paragraph (j)(2) of this AD. Do all related investigative and corrective actions before further flight. Repeat the detailed inspection thereafter at the applicable intervals specified in paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 747–53A2887, dated December 2, 2015.

(j) Exceptions to the Service Information

(1) Where Boeing Alert Service Bulletin 747–53A2887, dated December 2, 2015, specifies a compliance time "after the original issue date of this service bulletin," this AD requires compliance within the specified compliance time after the effective date of this AD.

(2) If any crack is found during any inspection required by this AD, and Boeing Alert Service Bulletin 747–53A2887, dated December 2, 2015, specifies to contact Boeing for appropriate action, and specifies that action as "RC" (Required for Compliance): Before further flight, repair using a method approved in accordance with the procedures specified in paragraph (k) of this AD.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (l)(1) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) Except as required by paragraph (j)(2) of this AD: For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (k)(4)(i) and (k)(4)(ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(l) Related Information

(1) For more information about this AD, contact Nathan Weigand, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle ACO, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6428; fax: 425–917–6590; email: *Nathan.P.Weigand@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on July 21, 2016.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–17718 Filed 7–27–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–6990; Directorate Identifier 2016–NE–14–AD]

RIN 2120–AA64

Airworthiness Directives; Turbomeca S.A. Turboshaft Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Turbomeca S.A. Arriel 1, 1A, 1A1, 1A2, 1B, 1B2, 1C, 1C1, 1C2, 1D, 1D1, 1E, 1E2, 1K1, 1S, and 1S1 turboshaft engines. This proposed AD was prompted by an anomaly that occurred during the grinding operation required by modification TU376, which increases the clearance between the rear curvic coupling of the centrifugal impeller and the fuel injection manifold. This proposed AD would require removing the centrifugal impeller and replacing with a part eligible for installation. We are proposing this AD to prevent failure of the centrifugal impeller, uncontained centrifugal impeller release, damage to the engine, and damage to the helicopter.

DATES: We must receive comments on this NPRM by September 26, 2016.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* 202–493–2251.

For service information identified in this proposed AD, contact Turbomeca S.A., 40220 Tarnos, France; phone: 33 (0)5 59 74 40 00; fax: 33 (0)5 59 74 45 15. You may view this service information at the FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6990; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the mandatory continuing airworthiness information (MCAI), the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Philip Haberlen, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7770; fax: 781–238–7199; email: *philip.haberlen@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2016–6990; Directorate Identifier 2016–NE–14–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD 2016–0090, dated May 10, 2016 (referred to hereinafter as "the MCAI"), to correct an unsafe condition for the specified products. The MCAI states:

> Turbomeca reported an anomaly that was generated during the grinding operation associated to the application of modification TU376, which increases the clearance between the rear curvic coupling of the centrifugal impeller and the fuel injection manifold.
>
> This condition, if not corrected, could lead to crack initiation and propagation in the centrifugal impeller bore area, possibly resulting in centrifugal impeller failure, with consequent damage to, and reduced control of, the helicopter. To address this potential unsafe condition, the life of the affected centrifugal impellers was reduced and Turbomeca published Mandatory Service Bulletin (MSB) 292 72 0848 to inform operators about the life reduction and to provide instructions for the replacement of the affected centrifugal impellers.
>
> For the reasons described above, this AD requires replacement of each affected centrifugal impeller before it exceeds the applicable reduced life limit.

You may obtain further information by examining the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6990.

Related Service Information

Turbomeca S.A. has issued Mandatory Service Bulletin (MSB) 292 72 0848, Version B, dated April 13, 2016. The MSB describes procedures for reducing the life limit of the centrifugal impellers affected by an anomaly that occurred during the grinding operation required by modification TU376. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of France, and is approved for operation in the United States. Pursuant to our bilateral agreement with the European Community, EASA has notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information provided by EASA and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design. This proposed AD would require removal of the centrifugal impeller from service before exceeding the reduced life limit shown in Appendix 1 of EASA AD 2016–0090, dated May 10, 2016, and replacement with a part eligible for installation.

Costs of Compliance

We estimate that this proposed AD affects 3 engines installed on helicopters of U.S. registry. We also estimate that it would take about 22 hours per engine to comply with this proposed AD. The average labor rate is $85 per hour. Required parts cost about $96,518 per engine. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $295,164.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a "significant regulatory action" under Executive Order 12866,

(2) Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Turbomeca S.A.: Docket No. FAA–2016–6990; Directorate Identifier 2016–NE–14–AD.

(a) Comments Due Date

We must receive comments by September 26, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to certain Arriel 1, 1A, 1A1, 1A2, 1B, 1B2, 1C, 1C1, 1C2, 1D, 1D1, 1E, 1E2, 1K1, 1S, and 1S1 turboshaft engines, with modification TU376 installed.

(d) Reason

This AD was prompted by an anomaly that occurred during the grinding operation required by modification TU376, which increases the clearance between the rear curvic coupling of the centrifugal impeller and the fuel injection manifold. We are issuing this AD to prevent failure of the centrifugal impeller, uncontained centrifugal impeller release, damage to the engine, and damage to the helicopter.

(e) Actions and Compliance

Comply with this AD within the compliance times specified, unless already done.

(1) Remove from service, any centrifugal impeller listed in Table 1 to paragraph (e) of this AD, before exceeding the applicable cycles since new (CSN) and replace with a centrifugal impeller not listed in Table 1 to paragraph (e) of this AD.

TABLE 1 TO PARAGRAPH (e)—CENTRIFUGAL IMPELLER CSNs

Part No.	Serial No.	CSN
0292254040	44	5,129
0292254040	1762FT	11,476
0292254050	1676CAR	6,281
0292254050	5333OTT	5,495
0292254050	5017OTT	5,491
0292254050	1136CAR	8,734
0292254050	3655OTT	4,600
0292254050	1757CAR	7,913
0292254050	1738CAR	10,640
0292254050	1149CAR	12,273
0292254050	2677OTT	11,145
0292254050	3109OTT	10,662
0292254050	3496OTT	5,562
0292254050	2074CAR	7,423
729225293A	290CAR	6,326
729225293A	1227FT	8,139
729225293A	504FB	4,600
729225293A	2517OTT	9,732
729225293A	2165OTT	6,163
729225293A	2194FT	11,461
729225293A	1331OTT	12,513
729225293A	1301FT	7,262
729225293A	1567FT	6,305
729225293A	783FB	8,307
729225293A	98OTT	9,492

(2) Reserved.

(f) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request. You may email your request to: *ANE-AD-AMOC@faa.gov.*

(g) Related Information

(1) For more information about this AD, contact Philip Haberlen, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7770; fax: 781–238–7199; email: *philip.haberlen@faa.gov.*

(2) Refer to MCAI, European Aviation Safety Agency AD 2016–0090, dated May 10, 2016, for more information. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2016–6990.

(3) Turbomeca S.A. Mandatory Service Bulletin (MSB) 292 72 0848, Version B, dated April 13, 2016, can be obtained from Turbomeca S.A., using the contact information in paragraph (g)(4) of this proposed AD.

(4) For service information identified in this proposed AD, contact Turbomeca S.A., 40220 Tarnos, France; phone: 33 (0)5 59 74 40 00; fax: 33 (0)5 59 74 45 15.

(5) You may view this service information at the FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Issued in Burlington, Massachusetts, on July 21, 2016.

Colleen M. D'Alessandro,

Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2016–17719 Filed 7–27–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–8180; Directorate Identifier 2016–NM–083–AD]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Bombardier, Inc. Model CL–600–2C10 (Regional Jet Series 700, 701, & 702) airplanes, Model CL–600–2D15 (Regional Jet Series 705) airplanes, Model CL–600–2D24 (Regional Jet Series 900) airplanes, and Model CL–600–2E25 (Regional Jet Series 1000) airplanes. This proposed AD was prompted by a determination that the protective polyurethane tapes applied to the upper surfaces of the aluminum and titanium floor structural members may not be trimmed properly, and on some places may overhang the profiles of the floor structural parts. Subsequent tests revealed that the overhanging pieces of tapes that are not bonded to the structure do not meet the flammability requirements and may allow fire propagation below the floor structure. This proposed AD would require an inspection of the polyurethane protective tapes installed on the floor structure for excess tape or incorrect tape installation, and corrective actions if necessary. We are proposing this AD to detect and correct overhanging pieces of protective polyurethane tapes, which are not bonded to the structure and do not meet the flammability requirements; this condition may allow fire propagation below the floor structure.

DATES: We must receive comments on this proposed AD by September 12, 2016.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com;* Internet *http://www.bombardier.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8180; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Fabio Buttitta, Aerospace Engineer, Airframe and Mechanical Systems Branch, ANE–171, FAA, New York Aircraft Certification Office (ACO), 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7303; fax 516–794–5531.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2016–8180; Directorate Identifier 2016–NM–083–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian Airworthiness Directive CF–2016–14, dated May 18, 2016 (referred to after this as the Mandatory Continuing Airworthiness Information, or "the MCAI"), to correct an unsafe condition for certain Bombardier, Inc. Model CL–600–2C10 (Regional Jet Series 700, 701, & 702) airplanes, Model CL–600–2D15 (Regional Jet Series 705) airplanes, Model CL–600–2D24 (Regional Jet Series 900) airplanes, and Model CL–600–2E25 (Regional Jet Series 1000) airplanes. The MCAI states:

> An inspection revealed that the protective polyurethane tapes applied to the upper surfaces of the aluminum and titanium floor structural members installed on CRJ 700/900/1000 aeroplanes may not be trimmed properly and on some places may overhang the profiles of the floor structural parts. Subsequent tests revealed that the overhanging pieces of tapes which are not bonded to the structure, do not meet the flammability requirements. If not corrected, this condition may allow fire propagation below the floor structure.
>
> This [Canadian] AD was issued to mandate the [detailed] inspection and removal of any excessive pieces of overhanging tape [or replacing incorrectly installed tape] found on the floor structure.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8180.

Related Service Information Under 1 CFR Part 51

Bombardier has issued Service Bulletin 670BA–53–055, dated December 3, 2015. The service information describes procedures for inspecting the polyurethane protective tapes for any excess tape or incorrect tape installation on the floor structure and corrective actions, which include removing any excess tape or replacing any incorrect tape installation found. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of these same type designs.

Costs of Compliance

We estimate that this proposed AD affects 569 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection and repair	190 work-hours × $85 per hour = $16,150	$0	$16,150	$9,189,350

The repair is done at the same time as the inspection. Therefore, we have not specified separate on-condition repair costs.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Bombardier, Inc.: Docket No. FAA–2016–8180; Directorate Identifier 2016–NM–083–AD.

(a) Comments Due Date

We must receive comments by September 12, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the Bombardier, Inc. airplanes identified in paragraphs (c)(1), (c)(2), and (c)(3) of this AD, certificated in any category.

(1) Model CL–600–2C10 (Regional Jet Series 700, 701, & 702) airplanes, serial numbers 10002 through 10342 inclusive.

(2) Model CL–600–2D15 (Regional Jet Series 705) airplanes and Model CL–600–2D24 (Regional Jet Series 900) airplanes, serial numbers 15001 through 15347 inclusive.

(3) Model CL–600–2E25 (Regional Jet Series 1000) airplanes, serial numbers 19001 through 19040 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Reason

This AD was prompted by a determination that the protective polyurethane tapes applied to the upper surfaces of the aluminum and titanium floor structural members may not be trimmed properly, and on some places may overhang the profiles of the floor structural parts. Subsequent tests revealed that the overhanging pieces of tapes that are not bonded to the structure do not meet the flammability requirements and may allow fire propagation below the floor structure. We are issuing this AD to detect and correct overhanging pieces of protective polyurethane tapes, which are not bonded to the structure and do not meet the flammability requirements; this condition may allow fire propagation below the floor structure.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Inspection and Corrective Actions

Within 12,600 flight hours after the effective date of this AD: Do a detailed visual inspection for excess tape or incorrect tape installation of the polyurethane protective tapes installed between floor panels and floor structure between fuselage station (FS) 280.00 and FS969.00; and do all applicable corrective actions; in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 670BA–53–055, dated December 3, 2015, except as specified in paragraph (h) of this AD. Do all applicable corrective actions before further flight.

(h) Exception to Service Information

Where Bombardier Service Bulletin 670BA–53–055, dated December 3, 2015, specifies to contact Bombardier, Inc., to "get an approved disposition to complete this service bulletin," before further flight, repair using a method approved by the Manager, New York ACO, ANE–170, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO).

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York Aircraft Certification Office (ACO), ANE–170, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the ACO, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, New York ACO, ANE–170, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(j) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian Airworthiness Directive CF–2016–14, dated May 18, 2016, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8180.

(2) For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com;* Internet *http://www.bombardier.com*. You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on July 21, 2016.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–17717 Filed 7–27–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 2 and 38

[Docket No. RM05–5–025]

Standards for Business Practices and Communication Protocols for Public Utilities

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Energy Regulatory Commission (Commission) proposes to incorporate by reference the latest version (Version 003.1) of certain Standards for Business Practices and Communication Protocols for Public Utilities adopted by the Wholesale Electric Quadrant (WEQ) of the North American Energy Standards Board (NAESB). These standards mainly modify and update NAESB's WEQ Version 003 Standards. The Commission also proposes to revise its regulations to incorporate NAESB's updated Smart Grid Business Practice Standards in the Commission's General Policy and Interpretations.

DATES: Comments are due September 26, 2016.

ADDRESSES: Comments, identified by Docket No. RM05–5–025, may be filed in the following ways:

- *Electronic Filing through http://www.ferc.gov.* Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format.
- *Mail/Hand Delivery:* Those unable to file electronically may mail or hand-deliver comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

Instructions: For detailed instructions on submitting comments and additional information on the rulemaking process, see the Comment Procedures Section of this document.

FOR FURTHER INFORMATION CONTACT:

Michael P. Lee (technical issues), Office of Energy Policy and Innovation, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–6548.

Gary D. Cohen (legal issues), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–8321.

SUPPLEMENTARY INFORMATION:

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1. In this notice of proposed rulemaking (NOPR), the Federal Energy Regulatory Commission (Commission) proposes to amend its regulations under the Federal Power Act[1] to incorporate by reference the latest version of certain Standards for Business Practices and Communication Protocols for Public Utilities (Version 003.1) adopted by the Wholesale Electric Quadrant (WEQ) of the North American Energy Standards Board (NAESB) and filed with the Commission on October 26, 2015 (October 26 Filing). We also propose to list informationally, as guidance, NAESB's updated Smart Grid Business Practice Standards in Standard WEQ–019. In addition, as explained further below, there are several NAESB standards included in the WEQ Version 003.1 package of standards that we are not proposing in this NOPR to incorporate by reference.

2. These revised NAESB standards update earlier versions of these standards that the Commission previously incorporated by reference into its regulations at 18 CFR 38.1 in

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[1] 16 U.S.C. 791a, *et seq.*

Order Nos. 676–E,[2] 676–H,[3] 764,[4] and 890.[5] In addition, NAESB developed two new suites of standards in coordination with the North American Electric Reliability Corporation (NERC) (the Commission-certified "electric reliability organization" responsible for developing and enforcing mandatory Reliability Standards).[6] These two NAESB proposals would establish: (1) NAESB Electric Industry Registry (EIR) business practice standards that replace the NERC Transmission System Information Networks (TSIN) as the tool to be used by wholesale electric markets to conduct electronic transactions via electronic tagging (e-Tags); and (2) Modeling Business Practice Standards to support and complement NERC's proposed retirement of its "MOD A" Reliability Standards.[7]

3. NAESB's WEQ Version 003.1 Business Practice Standards include modifications to the following set of existing standards:[8]

WEQ	Business practice standards
000	Abbreviations, Acronyms, and Definition of Terms.
001	Open Access Same-Time Information System (OASIS).
002	OASIS Standards and Communication Protocols (S&CP).
003	OASIS S&CP Data Dictionaries.
004	Coordinate Interchange.
006	Manual Time Error Corrections.
012	Public Key Infrastructure (PKI).
013	OASIS Implementation Guide.
019	Customer Energy Usage Information Communication.

4. Additionally, the Version 003.1 standards include two new suites of standards:

WEQ	Business practice standards
022	Electric Industry Registry (EIR).
023	Modeling.

5. These NAESB standards, developed through the NAESB standards development process or the NAESB minor correction process, build upon the Version 003 WEQ Business Practice Standards that NAESB filed with the Commission on September 18, 2012 and that the Commission incorporated by reference into its regulations in Order No. 676–H, a final rule issued by the Commission on September 18, 2014.[9]

I. Background

6. NAESB is a non-profit standards development organization established in late 2001 (as the successor to the Gas Industry Standards Board (GISB), which was established in 1994) and serves as an industry forum for the development of business practice standards and communication protocols for the wholesale and retail natural gas and electricity industry sectors. Since 1995, NAESB and its predecessor, the GISB, have been accredited members of the American National Standards Institute (ANSI), complying with ANSI's requirements that its standards reflect a consensus of the affected industries.[10]

7. NAESB's standards include business practices intended to standardize and streamline the transactional processes of the natural gas and electric industries, as well as communication protocols and related standards designed to improve the efficiency of communication within each industry. NAESB supports all three quadrants of the gas and electric industries—wholesale gas, wholesale electric, and retail markets quadrant.[11] All participants in the gas and electric industries are eligible to join NAESB and participate in standards development.

8. NAESB develops its standards under a consensus process so that the standards draw support from a wide range of industry members. NAESB's procedures are designed to ensure that all persons choosing to participate can have input into the development of a standard, regardless of whether they are members of NAESB, and each standard NAESB adopts is supported by a consensus of the relevant industry segments. Standards that fail to gain consensus support are not adopted. NAESB's consistent practice has been to submit a report to the Commission after it has made revisions to existing business practice standards or has developed and adopted new business practice standards. NAESB's standards are voluntary standards, which become mandatory for public utilities upon incorporation by reference by the Commission.

9. In Order No. 676,[12] the Commission not only incorporated by reference into its regulations business practice standards and communication protocols

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[2] *Standards for Business Practices and Communication Protocols for Public Utilities,* Order No. 676–E, 74 FR 63288 (Dec. 3, 2009), FERC Stats. & Regs. ¶ 31,299 (2009).

[3] *Standards for Business Practices and Communication Protocols for Public Utilities,* Order No. 676–H, 79 FR 56939 (Sept. 24, 2014), FERC Stats. & Regs. ¶ 31,359, at n.81 (2014), *corrected,* 149 FERC ¶ 61,014 (2014).

[4] *Integration of Variable Energy Resources,* Order No. 764, 77 FR 41,482 (July 13, 2012), FERC Stats. & Regs. ¶ 31,331 (2012).

[5] *Preventing Undue Discrimination and Preference in Transmission Service,* Order No. 890, 72 FR 12266 (Mar. 15, 2007), FERC Stats. & Regs. ¶ 31,241 (2007).

[6] NERC is the Commission-certified "electric reliability organization" responsible for developing and enforcing mandatory Reliability Standards. *See* section 215 of the Federal Power Act, 16 U.S.C. 824o (2012).

[7] In a February 19, 2014 petition, NERC proposed to retire Reliability Standards MOD–001–1a, MOD–004–1, MOD–008–1, MOD–028–2, MOD–029–1a, and MOD–030–2 and requested approval of new Reliability Standard MOD–001–2. Generally, the "MOD" series of NERC Reliability Standards pertain to transmission system modeling. The Commission issued a NOPR in Docket No. RM14–7–000 that addressed NERC's proposal, and the matter is currently pending before the Commission. *Modeling, Data, and Analysis Reliability Standards, Notice of Proposed Rulemaking,* 79 FR 36269 (June 26, 2014), 147 FERC ¶ 61,208 (2014) (MOD NOPR).

[8] On October 26, 2015, NAESB filed a report with the Commission (previously referenced as the October 26 Filing) presenting all the modifications it has made to the WEQ Version 003 Business Practice Standards since those standards were incorporated by reference by the Commission in 2014 in Order No. 676–H, as well as two new suites of standards that it has developed, which are further described below in P 12.

[9] *See supra* n.3.

[10] Prior to the establishment of NAESB in 2001, the Commission's development of business practice standards for the wholesale electric industry was aided by two *ad hoc* industry working groups established during the rulemaking proceeding that resulted in issuance of Order No. 889 and the creation of the OASIS, while GISB's efforts involved the development of business practice standards for the wholesale natural gas industry. Once formally established, NAESB took over the standards development previously handled by GISB and by the electric working groups.

[11] The retail gas quadrant and the retail electric quadrant were combined into the retail markets quadrant. NAESB continues to refer to these working groups as "quadrants" even though there are now only three quadrants.

[12] *Standards for Business Practices and Communication Protocols for Public Utilities,* Order No. 676, FERC Stats. & Regs. ¶ 31,216 (2006).

for the wholesale electric industry, it also established a formal ongoing process for reviewing and upgrading the Commission's OASIS standards and other wholesale electric industry business practice standards. In later orders in this series, the Commission incorporated by reference revisions to these standards.[13]

10. The WEQ Version 003.1 Business Practice Standards include six OASIS-related standards [14] that NAESB modified in response to directives and guidance provided in Order Nos. 676–E, 676–H, and 890. Specifically, in response to the Commission's guidance in Order No. 676–E, NAESB modified its OASIS standards to explicitly permit a transmission provider to extend the performance of the biennial assessment. In response to the Commission's guidance in Order No. 676–H, NAESB made four modifications to the OASIS suite of standards regarding: (1) The treatment of redirects for transmission service from conditional parent reservations; (2) the one-day requirement for the posting of Available Transfer Capability (ATC) Narratives; (3) the treatment of point-to-point reservations under Service Across Multiple Transmission Systems (SAMTS); and (4) the clarification of the requirements under which a transmission provider may deny a request to terminate service. To implement Commission guidance in Order No. 890, NAESB modified standards to allow for the consistent posting of Available Flowgate Capability (AFC) related data on OASIS sites.

11. In addition, as part of the standards development process, NAESB made two additional revisions to the OASIS suite of standards that were not made in response to Commission orders. First, NAESB modified WEQ–001 and WEQ–013 to require resellers to enter off-OASIS resale transactions into OASIS sites in the "accepted" status to provide the assignee of the resale the opportunity to confirm the transaction on the OASIS. Second, NAESB revised WEQ–002–4.3.6.2 to allow for the unmasking of the source and sink of a request for transmission when that request is moved to any final state.

12. NAESB has adopted certain new and revised WEQ Version 003.1 Business Practice Standards based on developments involving NERC. First, NAESB developed the WEQ–022 Electric Industry Registry (EIR) Business Practice Standards to complement the transfer of registry functions from the NERC TSIN to the NAESB EIR. The EIR database serves as a central repository of information required for commercial interactions, including electronic transactions via e-Tags. Second, NAESB developed the WEQ–023 Modeling Business Practice Standards in response to a NERC petition to delete and retire the six "MOD A" Reliability Standards. As mentioned above, NERC filed a petition with the Commission on February 10, 2014 proposing to retire NERC's six MOD A Reliability Standards and replace them with Reliability Standard MOD–001–2, which NERC states will focus exclusively on the reliability aspects of ATC and AFC.[15] On February 7, 2014, NERC submitted a request to NAESB (Standards Request 14002) [16] asking NAESB to consider adopting standards that address the commercial and business aspects of the MOD standards proposed for retirement. NAESB subsequently developed the WEQ–023 Business Practice Standards to support and complement the proposed retirement of the MOD A Reliability Standards. The WEQ–023 Business Practice Standard specifies the requirements for calculating ATC and AFC and supports the task of reporting on the commercial aspects of these calculations.[17]

13. Third, NAESB has adopted revisions to NAESB standards that need to match up with NERC's Interchange Scheduling and Coordination (INT) Reliability Standards. In this regard, NAESB modified certain WEQ–000 and WEQ–004 Business Practice Standards to complement NERC's proposal to modify the INT Reliability Standards, including removal of the Load Serving Entity (LSE) category as one of the functional registration categories in the NERC Compliance Registry.[18]

14. NAESB also includes as part of its Version 003.1 Business Practice Standards additional non-OASIS standards modifications to WEQ Version 003.1 that it made in the course of normal standards development. In Order No. 764, the Commission required transmission providers to provide for the scheduling of interchange in 15-minute intervals. In response, NAESB made two changes to the WEQ–004 Coordinate Interchange Business Practice Standards. NAESB also modified WEQ–019 to ensure consistency between WEQ Business Practice Standards and other standards organizations' standards. Additionally, NAESB modified WEQ–000 to harmonize definitions with NAESB Retail Market Quadrant efforts.

15. In Order 676–H, the Commission incorporated by reference WEQ Business Practice Standards to support Public Key Infrastructure (PKI). The WEQ Version 003.1 Business Practice Standards include additional PKI modifications to WEQ–002, WEQ–004, and WEQ–012 to support the NAESB Authorized Certification Authority (Certification Authority) Certification Program and to account for technological advances.

16. NAESB also has in place a process to make necessary minor corrections to its standards, when needed. The WEQ Version 003.1 Business Practice Standards include seven new minor corrections made by NAESB.[19]

II. Discussion

17. As discussed below, with certain enumerated exceptions, we propose to incorporate by reference (into the Commission's regulations at 18 CFR 38.1(b)) the NAESB WEQ Version 003.1 Business Practice Standards.[20] The Version 003.1 standards will replace the Version 003 standards currently incorporated by reference into the Commission's regulations. Where we have proposed in this NOPR to incorporate a NAESB Business Practice

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[13] *Standards for Business Practices and Communication Protocols for Public Utilities,* Order No. 676–C, FERC Stats. & Regs. ¶ 31,274, *reh'g denied,* Order No. 676–D, 124 FERC ¶ 61,317 (2008); *See supra* n.2; *Standards for Business Practices and Communication Protocols for Public Utilities,* Order No. 676–F, FERC Stats. & Regs. ¶ 31,309 (2010); *Standards for Business Practices and Communication Protocols for Public Utilities,* Order No. 676–G, 78 FR 14654 (Mar. 7, 2013), FERC Stats. & Regs. ¶ 31,343 (2013); *See supra* n.3.

[14] The OASIS suite of standards is used collectively by NAESB to reference four business practice standards: WEQ–001 Open Access Same-Time Information System (OASIS); WEQ–002 OASIS Standards and Communication Protocols (S&CP); WEQ–003 OASIS S&CP Data Dictionaries; and WEQ–013 OASIS Implementation Guide.

[15] As mentioned above, NERC proposes to retire Reliability Standards MOD–001–1a, MOD–004–1, MOD–008–1, MOD–028–2, MOD–029–1a, and MOD–030–2.

[16] *https://www.naesb.org/pdf4/r140.*

[17] These terms are defined in WEQ–000–1.

[18] NAESB October 26 Filing at 3.

[19] These corrections are identified and explained in the October 26 Filing.

[20] Consistent with our past practice, we do not propose to incorporate by reference into the Commission's regulations the following standards: Standards of Conduct for Electric Transmission Providers (WEQ–009); Contracts Related Standards (WEQ–010); and WEQ/WGQ eTariff Related Standards (WEQ–014). We also do not propose to incorporate by reference at this time the WEQ–023 Modeling Business Practice Standards. We do not propose to incorporate by reference standard WEQ–009 because it contains no substantive standards and merely serves as a placeholder for future standards. We do not propose to incorporate by reference standard WEQ–010 because this standard contains an optional NAESB contract regarding funds transfers and the Commission does not require utilities to use such contracts. Moreover, as discussed more specifically in the section below on Redirects from Conditional Parent Reservations, we do not propose in this NOPR to incorporate by reference certain portions of WEQ–001.

Standard by reference into the Commission's regulations, this has been based on a preliminary determination that the standard at issue is consistent with the Commission's findings in Order No. 676–H and does not appear inconsistent with any Commission directives or findings in other orders.

A. Revisions to WEQ OASIS Business Practice Standards in Light of Commission Policies

1. Overview

18. The NAESB WEQ Version 003.1 Business Practice Standards contain six modifications to the OASIS suite of standards that NAESB developed to ensure consistency with certain policies articulated by the Commission in Order Nos. 676–H, 676–E, and 890. NAESB states that four of the six modifications align the OASIS suite of standards with guidance provided by the Commission in Order No. 676–H concerning the treatment of redirects for transmission service from conditional parent reservations, the one-day requirement for the posting of ATC Narratives, the treatment of point-to-point reservations under SAMTS, and new clarification of the requirements under which a transmission provider may deny a request to terminate service. In response to a directive in Order No. 676–E, NAESB also modified standards to explicitly permit a transmission provider to extend the performance of the biennial reassessment. Additionally, to implement the Commission's guidance provided in Order No. 890, NAESB modified pertinent standards to allow for the consistent posting of AFC-related data on OASIS sites.

2. Redirects From Conditional Parent Reservations

19. In Order No. 676–H, the Commission declined to incorporate by reference NAESB Standards WEQ–001–9.5 and WEQ–001–10.5. The Version 003.0 WEQ–001–9.5 stated that, "upon confirmation of the request to Redirect on a firm basis, the Capacity Available to Redirect shall be reduced by the amount of the redirected capacity granted for the time period of that Redirect." The Version 003.0 WEQ–001–10.5 contained nearly identical language relating to the confirmation of requests to redirect on a non-firm basis. The Commission explained that it found both of these standards inconsistent with the Commission's precedent in *Dynegy Power Marketing, Inc.*[21] and *Entergy Services, Inc.*[22] With regard to Standard WEQ–001–9.5, the Commission explained that, "as we found in these orders, reducing the capacity available to redirect prior to the passage of the conditional reservation deadline could lead to a customer paying firm transmission charges and losing capacity on both its original path and its redirect path."[23] The Commission further explained that the *Dynegy* policy "effects a reasonable balancing of interests between the customer and the transmission owner by ensuring that the customer does not potentially lose rights to capacity, while at the same time still permitting the transmission owner to sell available capacity on a short term basis until the redirect becomes unconditional." The Commission also found that Standard WEQ–001–10.5 raised similar concerns regarding the confirmation of requests to redirect on a non-firm basis and also declined to incorporate by reference Standard WEQ–001–10.5 and requested that NAESB, likewise, give consideration to reworking this standard.

20. As the Commission stated in *Entergy*,[24] our guiding precedent on the issue of when a customer requesting redirect loses rights on the original path was set in *Dynegy*.[25] In *Dynegy*, the Commission found that a transmission customer receiving firm transmission service does not lose its rights to its original path until the redirect request satisfies all of the following criteria: (1) It is accepted by the transmission provider; (2) it is confirmed by the transmission customer; and (3) it passes the conditional reservation deadline under section 13.2 of its Open Access Transmission Tariff.

21. Having NAESB revise its standards to accommodate the Commission's policy in this area will help avoid confusion by public utilities as to their responsibilities under the Commission's policy and under the NAESB standards. The Commission's concern in *Dynegy* and *Entergy* was that a redirecting customer would lose its rights to the unconditional parent path and be left with no transmission service during the redirect period if the requested redirect was preempted by a competing service request.

22. We appreciate the extensive work that NAESB and its stakeholder have undertaken in response to our directive in Order 676–H. NAESB has reached consensus on standards relating to redirects related to unconditional parent reservations, and we propose to incorporate those standards by reference into our regulations.

23. NAESB reports, however, that it was unsure whether and to what extent the *Dynegy* policy applies to conditional parent reservations and non-firm service, and no consensus could be reached with respect to such standards. It therefore adopted a standard (WEQ–001–9.5) that allows individual transmission providers to craft provisions in their individual tariffs for how they will address redirects of requests for firm transmission service, rather than having an industry-wide business practice for such transactions. Because it could not reach consensus on these issues, the standards also do not prescribe when a public utility must reduce uncommitted capacity to account for redirects. NAESB also adopted a similar rewrite of the standard (WEQ–001–10.5) on redirects on a non-firm basis.

24. The concern about the negative effects of the potential loss of the customer's parent path when the parent reservation is conditional and subject to competition arguably is much less compelling than when the parent reservation is unconditional. While *Dynegy* carved out an exception for unconditional parent reservations, the Commission has not explicitly ruled on whether *Dynegy* applies to conditional parent reservations, and such an extension may go beyond the policy concern with losing firm service articulated in *Entergy*.

25. We, therefore, invite comment on whether the Commission should apply the *Dynegy* policy to conditional and non-firm redirects. Parties also should address the four redirect-related issues on which stakeholders have been unable to reach consensus. These are: (1) The treatment of a firm redirect for transmission service following the preemption of the conditional parent reservation; (2) the circumstances under which a firm redirect for transmission service may return to the conditional parent reservation; (3) the number of subsequent firm redirects for transmission service that can stem from the original firm redirect for transmission service; and (4) the proper treatment of requests to redirect requests for non-firm transmission service. Based on these responses, the Commission will consider whether it will adopt regulations regarding redirects from conditional parent reservations and non-firm service.

3. Requirement To Post ATC Narrative Within One Day

26. NAESB developed Standard WEQ–001–14 to meet the requirement

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[21] 99 FERC ¶ 61,054, at P 9 (2002) (*Dynegy*).

[22] 143 FERC ¶ 61,143, at P 25 & n.68 (2013) (*Entergy*).

[23] *Id.* P 47.

[24] *Id.* P 25 & n.68.

[25] *Dynegy*, 99 FERC ¶ 61,054 at P 9.

in Order No. 890 for transmission providers to post a narrative in instances when ATC remains unchanged at a value of zero for six months or longer. In addition, Standard WEQ–001–15 requires transmission providers to post a brief narrative that explains the reason for a change in monthly or yearly ATC values on a constrained path when a monthly or yearly ATC value changes as a result of a 10 percent change in total transfer capability. In Order No. 676–H, the Commission declined to incorporate by reference Standards WEQ–001–14.1.3 and WEQ–011–15.1.2 after determining that these standards did not meet the Commission's requirement to post the ATC narrative as soon as feasible.[26] The Commission requested that NAESB "revise these standards to provide for a one-day posting requirement."[27] In response, NAESB modified Standards WEQ–001–14.1.3 and WEQ–011–15.1.2 and adopted business practice standards to support the one-day posting requirement.

27. NAESB's revised standards appear consistent with our findings in Order No. 676–H and do not appear inconsistent with any Commission directives or findings in other orders. Moreover, as we explained above,[28] below,[29] and in previous orders, the NAESB standards are developed in an open consensus process that assures that the standards draw support from a wide range of industry members before being developed and adopted. Accordingly, we propose to incorporate by reference, into the Commission's regulations at 18 CFR 38.1, NAESB's revised standards on the timing of the required posting of ATC narratives, as set forth in NAESB's WEQ Version 003.1 Business Practice Standards.

4. SAMTS Point-to-Point Treatment

28. The NAESB SAMTS business practice standards that the Commission incorporated by reference in Order No. 676–H were developed in response to a Commission finding in Order No. 890 requesting that NAESB develop business practice standards in this area.[30] In Order No. 676–H, the Commission found reasonable a NAESB request to treat a conditional point-to-point reservation included in a coordinated group displaced through preemption as comparable to a reservation being superseded as a result of preemption.[31] NAESB therefore includes in the Version 003.1 standards modifications to the SAMTS-related standards to permit a customer with preempted transmission capacity from a reservation associated with a coordinated group to alter (reduce or terminate) the capacity of coordinate requests in the coordinated group.

29. The Commission finds that NAESB's revised standards are consistent with our findings in Order No. 676–H and do not appear inconsistent with any Commission directives or findings in other orders. Accordingly, we propose to incorporate by reference, into the Commission's regulations at 18 CFR 38.1, NAESB's revised standards on SAMTS-Related standards as set forth in the WEQ Version 003.1 Business Practice Standards.

5. Clarification of Discretion of Transmission Providers To Deny Service Requests Under Standard WEQ–001–106.2.5

30. In Order No. 676–H, the Commission declined to incorporate by reference Standard WEQ–001–106.2.5, explaining that the standard was "unclear in its application and could be read to allow Transmission Providers discretion to deny requests to terminate service in situations where this might not be warranted."[32] In response, NAESB modified Standard WEQ–001–106.2.1, added Standard WEQ–001–106.2.1.1, and deleted Standard WEQ–001–106.2.5. Together, these revised standards clarify that a transmission customer should submit an accurate termination request and, if the transmission customer fails to do so, the transmission provider may deny the request.

31. NAESB's revised standards appear consistent with our findings in Order No. 676–H and do not appear inconsistent with any Commission directives or findings in other orders. Accordingly, we propose to incorporate by reference, into the Commission's regulations at 18 CFR 38.1, NAESB's revised Standards WEQ–WEQ–001–106.2.21, WEQ–001–106.2.1.1, and WEQ–001–106.2.5, as set forth in the WEQ Version 003.1 Business Practice Standards.

6. Modifications To Allow a Transmission Provider To Extend the Time To Perform Its Biennial Reassessment

32. In Order No. 676–E, the Commission stated "we reiterate here the Commission's finding in Order No. 890 that a transmission provider is permitted to extend the timeframe to reassess the availability of conditional firm service. Since the Version 002.1 Standards do not specifically address this issue, we would ask the industry, working through NAESB, to continue to look at additional business practice standards facilitating a transmission provider's extension of its right to perform a reassessment."[33] In response to this request, NAESB, in its Version 003.1 Standards, adopted modifications to five standards in the WEQ–001 OASIS Business Practice Standards and one standard in the WEQ–013 OASIS Implementation Guide Business Practice Standards that explicitly allow a transmission provider to extend the deadline by which it must perform its biennial reassessment of the availability on its system of conditional firm service.

33. NAESB's revised standards appear consistent with our findings in Order No. 676–E and do not appear inconsistent with any Commission directives or findings in other orders. Accordingly, we propose to incorporate by reference, into the Commission's regulations at 18 CFR 38.1, NAESB's revisions to five standards to extend the deadline by which a transmission provider must perform its biennial reassessment of the availability on its system of conditional firm service, as set forth in the WEQ Version 003.1 Business Practice Standards.

7. Industry-Wide Mechanism for Consistent Posting of AFC-Related Data

34. In Order No. 890–A, the Commission explained that "[t]o the extent MidAmerican or its customers find it beneficial also to post AFC, MidAmerican is free to post both ATC and AFC values."[34] In the WEQ Version 003.1 Business Practice Standards, NAESB includes revisions to provide an industry-wide mechanism for posting of AFC-related data. NAESB adds three new data elements to the list of valid data element values for SYSTEM_ATTRIBUTE and SYSTEM_ELEMENT_TYPE in WEQ–003 OASIS Data Dictionary and to the system data OASIS template in WEQ–013 OASIS

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[26] Order No. 676–E, FERC Stats. & Regs. ¶ 31,299 at P 39.

[27] *Id.* P 29.

[28] *See supra* P 8.

[29] *See infra* P 57.

[30] Order No. 890, FERC Stats. & Regs. ¶ 31,241 at P 1377.

[31] Order No. 676–H, FERC Stats. & Regs. ¶ 31,359 at P 65.

[32] *Id.* P 58.

[33] Order No. 676–E, FERC Stats. & Regs. ¶ 31,299 at P 72.

[34] Order No. 890–A, FERC Stats. & Regs. ¶ 31,261 at P 51.

Implementation Guide Business Practice Standards.

35. NAESB's revised standards appear consistent with our findings in Order No. 890–A and do not appear inconsistent with any Commission directives or findings in other orders. Accordingly, we propose to incorporate by reference, into the Commission's regulations at 18 CFR 38.1, NAESB's revisions to the data elements in the OASIS Data Dictionary and to the data OASIS Template in Standard WEQ–013 to provide an industry-wide mechanism for posting of AFC-related data, as set forth in the WEQ Version 003.1 Business Practice Standards.

8. Use of DUNS Numbers

36. In Order No. 768, the Commission eliminated the requirement to use DUNS numbers[35] in Electronic Quarterly Report filings and stated that "DUNS numbers have proven to be imprecise identification systems, as entities may have multiple DUNS numbers, only one DUNS number, or no DUNS number at all."[36] NAESB has adopted revisions to Standard WEQ–001–3.1 to eliminate the use of a DUNS number to identify an organization in OASIS postings. For consistency, NAESB also adopted changes or modifications to the Standard WEQ–000 Abbreviations, Acronyms, and Definition of Terms Business Practice Standards, WEQ–001 OASIS Business Practice Standards, WEQ–003 OASIS Data Dictionary Business Practice Standards, and WEQ–013 OASIS Implementation Guide Business Practice Standards.

37. NAESB's revised standards appear consistent with the Commission's findings in Order No. 768 and do not appear inconsistent with any Commission directives or findings in other orders. Accordingly, we propose to incorporate by reference, into the Commission's regulations at 18 CFR 38.1, NAESB's revisions to Standard WEQ–002–4.3.6.2.

B. Revised and New Standards Designed To Complement NERC Reliability Standards and Developments

1. NERC Compliance Registry

38. The WEQ Version 003.1 standards include modifications to the WEQ–004 Coordinate Interchange Business Practice Standards to include in the EIR items eliminated by NERC, in Docket No. RR15–4–000, from the NERC Compliance Registry including the elimination of the LSE, the Purchase Selling Entity, and the Interchange Authority roles. This proposal was accepted by the Commission in orders issued on March 19, 2015[37] and on October 15, 2015.[38] Because the Commission has accepted the elimination of the LSE function from the NERC Compliance Registry, we propose to incorporate by reference, into the Commission's regulations at 18 CFR 38.1, the NAESB modifications of WEQ–004 pertaining to Coordinate Interchange Business Practices.

2. Electric Industry Registry Standards

39. On November 13, 2012, the NAESB EIR replaced the NERC TSIN as the industry registry, a tool previously used by wholesale electric markets to help them develop e-Tags for electronic scheduling. Thus, the NAESB EIR is now the tool the industry uses to support OASIS users in the electronic scheduling of transactions by acting as the central repository for information used by the wholesale electric industry in the creation of e-Tags. The WEQ–004 Coordinate Interchange Business Practice Standards and e-Tag Functional Specifications and Schema provide the commercial framework for e-Tagging. The new WEQ–022 EIR Business Practice Standards establish business practices for the NAESB EIR and provide guidance for registry users.

40. NAESB's revised Standard WEQ–004 appears reasonable and does not appear inconsistent with any Commission directives or findings in other orders. Accordingly, we propose to incorporate by reference, into the Commission's regulations at 18 CFR 38.1, NAESB's revised Standard WEQ–004 as set forth in the WEQ Version 003.1 Business Practice Standards.

3. WEQ–023 Modeling Business Practice Standards

41. WEQ's Version 003.1 Business Practice Standards includes a new suite of standards, the WEQ–023 Modeling Business Practice Standards, which address technical issues affecting the calculation of ATC for wholesale electric transmission services. NAESB developed these Modeling standards after NERC proposed to retire the bulk of its MOD A Reliability Standards, which address ATC calculation, and NERC requested that NAESB consider developing replacement Business Practice Standards for requirements that NERC identified as being potentially relevant for commercial purposes.[39] WEQ–023 includes two new requirements not previously included in the NERC Reliability Standards related to contract path management. These two standards, WEQ–023–1.4 and WEQ–023–1.4.1, limit the amount of firm transmission service across a path between balancing authorities to the contract path limit for that given path.

42. The Commission is considering NERC's proposed retirement of its ATC-related Reliability Standards in Docket No. RM14–7–000. In addition, the Commission has established a proceeding in Docket No. AD15–5–000 to consider proposed changes to the calculation of ATC, and has conducted a technical conference and received comments regarding such changes.[40] As a result, we are not proposing to incorporate by reference the WEQ–023 Modeling Business Practice Standards in this NOPR, but will consider these standards as part of the overall inquiry into ATC calculation.

C. Revisions to WEQ Business Practice Standards Not Requested by Commission or Developed To Comply With a Commission Directive

43. In addition to the standards revisions that NAESB made to comply with various Commission directives and requests, NAESB also developed and adopted five revisions to the Business Practice Standards at its own initiative. These revisions: (1) Introduce a requirement for resellers to post off-OASIS resale transactions on the OASIS in the "accepted" status to provide the assignee of the resale the opportunity to confirm the transaction on the OASIS; (2) allow for the unmasking of the source and sink of a request for transmission service, once that request is moved to any final state; (3) modify the Commission's existing non-mandatory guidance on Smart Grid standards; (4) modify the WEQ Abbreviations, Acronyms, and Definition of Terms in Standard WEQ–000 to maintain consistency between the defined terms used in the NAESB standards, including revisions to the

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[35] The Data Universal Numbering System, abbreviated as DUNS or D–U–N–S, is a proprietary system developed and regulated by Dun & Bradstreet that assigns a unique numeric identifier, referred to as a "DUNS number" to a single business entity.

[36] *Electricity Market Transparency Provisions of Section 220 of the Federal Power Act*, Order No. 768, 77 FR 61896, FERC Stats. & Regs. ¶ 31,336, at P 171 (2012).

[37] *North American Electric Reliability Corporation*, 150 FERC ¶ 61,213 (2015).

[38] *North American Electric Reliability Corporation*, 153 FERC ¶ 61,024, at P 20 (2015).

[39] NERC's proposal is currently pending before the Commission in the rulemaking proceeding in Docket No. RM14–7–000, *see supra* n.7.

[40] *See, e.g.*, the December 18, 2014 status report filed by NAESB in Docket Nos. RM05–5–000 and RM14–7–000, and the Commission's April 21, 2015 workshop, *Available Transfer Capability Standards for Wholesale Electric Transmission Services*, Docket No. RM15–5–000.

terms "Demand Reduction Value" and "Energy Efficiency" to mirror definitions proposed by the Retail Market Quadrant and prevent industry confusion; and (5) modify the Commission's PKI-related standards. We will now separately discuss each of these revisions.

1. Proper Method To Post Off-OASIS Resale Transactions

44. NAESB's WEQ Version 003.1 Business Practice Standards include a revision to the WEQ–013 OASIS Implementation Guide Business Practice Standards to allow off-OASIS resale transactions to be posted directly to the OASIS under an "accepted" status. Prior to the modification to WEQ–013–2.6.7.2, these transactions were posted only as confirmed transactions. NAESB has also adopted a revision to the WEQ–001 OASIS Business Practice Standards (WEQ–013–2.6.7.2) as a conforming change requiring a service agreement between an assignee and a transmission provider to be executed once the assignee has confirmed the resale transaction on the OASIS.

45. NAESB's revised standards on this subject appear reasonable and do not appear inconsistent with any directives or findings in any Commission orders. Accordingly, we propose to incorporate by reference, into the Commission's regulations at 18 CFR 38.1, NAESB's revisions to Standard WEQ–013–2.6.7.2 and to the WEQ–013 OASIS Implementation Guide Standards.

2. Unmasking of Final State Source and Sink Requests

46. NAESB's WEQ Version 003.1 Business Practice Standards modify Standard WEQ–002–4.3.6.2 to unmask the source and sink for a request for transmission service for all instances where the request for transmission service is moved to any final state. Prior to this modification, masking of the source and sink of a request for transmission service was permitted until the status of that request was confirmed.

47. NAESB's revised standards appear reasonable and do not appear inconsistent with any directives or findings in any Commission order. Accordingly, we propose to incorporate by reference, into the Commission's regulations at 18 CFR 38.1, NAESB's revisions to Standard WEQ–002–4.3.6.2.

3. Modifications to Smart Grid Standards

48. In Order 676–H, the Commission recognized the values of the Smart Grid standards and encouraged "further developments in interoperability, technological innovation and standardization in this area." In Order No. 676–H, the Commission adopted in its regulations as non-mandatory guidance five Smart Grid related standards: (1) WEQ–016 Specifications for Common Electricity Product and Pricing Definition Business Practice Standards; (2) WEQ–017 Specifications for Common Schedule Communication Mechanism for Energy Transactions; (3) WEQ–018 Specifications for Wholesale Standard Demand Response Signals Business Practice Standards; (4) WEQ–019 Customer Energy Usage Information Communication Business Practice Standards; and (5) WEQ–020 Smart Grid Standards Data Elements Table Business Practice Standards. This guidance is published in the **Federal Register** at 18 CFR 2.27.

49. In its Version 003.1 Business Practice Standards, NAESB has modified the Standard WEQ–019 Customer Energy Usage Information Communication Business Practice Standards. NAESB made this modification so that the revised standard will operate in harmony with other smart grid standards, including the Smart Energy Profile 2.0, the International Electrotechnical Commission Information Model, the NAESB REQ.21 Energy Service Providers Interface, and standards developed by the American Society of Heating, Refrigerating, and Air-Conditioning Engineers.

50. Standard WEQ–019 provides for energy usage information and this revision allows consumers access to their energy usage information. These standards will not only be used by the wholesale electric industry, but also are important initiatives for use in ongoing utility programs for consumer data access. We, therefore, propose to revise our non-mandatory guidance that we listed in 18 CFR 2.27(d) to reference NAESB's updated Standard WEQ–019 as set out in the Version 003.1 package of WEQ Business Practice Standards, replacing the existing reference in 18 CFR 2.27(d) to Standard WEQ–019 as set out in the Version 003 WEQ Business Practice Standards.

4. Modification to Standards on Abbreviations, Acronyms and Definitions of Terms

51. Also included in Version 003.1 is a modification to WEQ Abbreviations, Acronyms, and Definition of Terms in Standard WEQ–000 to maintain consistency between the defined terms used in the NAESB standards, and modified the terms "Demand Reduction Value" and "Energy Efficiency" to mirror definitions proposed by the Retail Market Quadrant and prevent industry confusion.

52. NAESB's revised standards appear reasonable and do not appear inconsistent with any directives or findings in any Commission orders. Accordingly, we propose to incorporate by reference, into the Commission's regulations at 18 CFR 38.1, NAESB's revisions to Standard WEQ–000.

5. Public Key Infrastructure-Related Standards

53. NAESB includes three modifications to support the WEQ–012 PKI Business Practice Standards previously incorporated by reference by the Commission in Order No. 676–H.[41] The three PKI-related modifications made in the Version 003.1 Standards were to the WEQ–012 PKI Business Practice Standards, the WEQ–002 OASIS Standards and Communication Protocols Business Practice Standards, and the WEQ–004 Coordinate Interchange Business Practice Standards. NAESB modified WEQ–012 to accommodate technology changes and security advances as well as to remove standards specifying criteria a certificate authority must meet. NAESB moved the standards specifying criteria that must be met out of the Version 003.1 Business Practice Standards and into a second document that outlines the prerequisites a certificate authority must meet to become a NAESB Certification Authority.[42]

54. NAESB modified five standards and added three standards WEQ–002, which require the use of a certificate issued by a NAESB Certification Authority to access an OASIS site and include requirements related to support the implementation of PKI on OASIS sites as well as revisions to reflect the transmission of the registry from the NERC TSI to the NAESB EIR. NAESB includes one new standard, WEQ–004–2.3, which requires all e-Tagging communication to be secured by certifications issued by a NAESB Certification Authority. NAESB also includes modifications to WEQ–000 for consistency purposes.

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[41] These three modifications were not included in the Version 003 filing NAESB made on September 18, 2012 but rather were filed separately by NAESB on January 29, 2013 following the conclusion of standards development. *See* Submittal of Modifications to the NAESB Public Key Infrastructure Standards and Other Standards to support the Public Key Infrastructure, Docket Nos. RM05–5–000 and RM05–5–022, January 29, 2013.

[42] The specifications document was created in recognition that certificate authorities may not be subject to the Commission's jurisdictional authority under the Federal Power Act and that specification requirements can be modified through an accelerated process versus standards development.

55. In Order No. 676–H, the Commission incorporated by reference the WEQ–012 PKI Business Practice Standards. In Version 003.1, NAESB has filed three modifications to support these standards, requesting that the Commission also incorporate by reference these modifications. We propose to incorporate these revised standards by reference into the Commission's regulations. These revised standards will require public utilities to conduct transactions securely when using the internet and will eliminate confusion over which transactions involving public utilities must follow the approved PKI procedures to secure their transactions. The revisions support the NAESB Authorized Certification Authority (ACA) Certification Program and account for technological advances following the original adoption of the standards by NAESB.[43]

D. Implementation

56. Consistent with the policy that we introduced in Order No. 676–H,[44] we propose upon issuance of a final rule, to establish a specific date by which all public utilities must file compliance filings revising their tariffs to acknowledge their responsibility to comply with the revised standards. In Order No. 676–H, we permitted public utilities that wish to incorporate the complete set of NAESB standards into their tariffs without modification to avoid having to make future compliance filings by specifying in their compliance filing that they are incorporating into their tariff all of the standards incorporated by reference by the Commission as specified in Part 38 of the Commission's Rules of Practice and Procedure as updated and revised. Those public utilities that followed this approach after the issuance of Order No. 676–H will not need to make a compliance filing revising their tariff after issuance of a final rule in this proceeding as long as they continue to incorporate all of the standards without modification. Public utilities that have not availed themselves of this option in complying with Order No. 676–H would be free to do so in complying with a final rule in this proceeding.

III. Notice of Use of Voluntary Consensus Standards

57. The NAESB WEQ Version 003.1 Business Practice Standards were adopted by NAESB under NAESB's consensus procedures.[45] As the Commission found in Order No. 676, adoption of consensus standards is appropriate because the consensus process helps ensure the reasonableness of the standards by requiring that the standards draw support from a broad spectrum of all segments of the industry. Moreover, since the industry itself has to conduct business under these standards, the Commission's regulations should reflect those standards that have the widest possible support. In section 12(d) of the National Technology Transfer and Advancement Act of 1995, Congress affirmatively requires federal agencies to use technical standards developed by voluntary consensus standards organizations, like NAESB, as a means to carry out policy objectives or activities unless use of such standards would be inconsistent with applicable law or otherwise impractical.[46]

58. Office of Management and Budget Circular A–119 (section 11) (February 10, 1998) provides that Federal Agencies should publish a request for comment in a NOPR when the agency is seeking to issue or revise a regulation proposing to adopt a voluntary consensus standard or a government-unique standard. In this NOPR, the Commission is proposing to incorporate by reference voluntary consensus standards developed by the WEQ of NAESB.

IV. Incorporation by Reference

59. The Office of the Federal Register requires agencies incorporating material by reference in final rules to discuss, in the preamble of the final rule, the ways that the materials it incorporates by reference are reasonably available to interested parties and how interested parties can obtain the materials.[47] The regulations also require agencies to summarize, in the preamble of the final rule, the material it incorporates by reference. The NAESB standards we are proposing to incorporate by reference in this Final Rule can be summarized as follows:

- *Revisions to OASIS Standards.* The Version 003.1 standards include revisions to six OASIS-related standards made to conform to directives and guidance provided by the Commission in Order Nos. 676–E, 676–H, and 890. In addition, NAESB modified WEQ–001 and WEQ–013 to require resellers to enter off-OASIS resale transactions into OASIS sites in the "accepted" status to provide the assignee of the resale the opportunity to confirm the transaction on the OASIS and revised WEQ–002–4.3.6.2 to allow for the unmasking of the source and sink of a request for transmission when that request is moved to any final state. Finally, NAESB modified WEQ–001, WEQ–003, and WEQ–013 to be consistent with the Commission's treatment of Data Universal Numbering System (DUNS) numbers.
- *Revisions to NERC-Related Standards.* NAESB modified existing standards and developed new standards based on developments involving NERC. In addition, NAESB has adopted revisions to NAESB standards that need to match up with NERC's Interchange Scheduling and Coordination (INT) Reliability Standards. The Commission is proposing to incorporate by reference the WEQ–022 standards and the standards relating to NERC's INT standards.[48]
- *Standards Development.* NAESB also modified four additional standards in the course of normal standards development. In response to Order No. 764, NAESB modified WEQ–004 to provide for the scheduling of interchange in 15-minute intervals and modified WEQ–019 to ensure consistency between WEQ Business Practice Standards and other standards organizations' standards. Additionally, NAESB modified WEQ–000 to harmonize definitions with NAESB Retail Market Quadrant efforts.
- *PKI Modifications.* The standards include additional PKI modifications to WEQ–002, WEQ–004, and WEQ–012 to support the NAESB Authorized Certification Authority (Certification Authority) Certification Program and to account for technological advances.
- *Minor Corrections.* Under its process to make necessary minor corrections to its standards, when needed, the WEQ Version 003.1 Business Practice Standards include seven new minor corrections made by NAESB.

60. Our regulations provide that copies of the NAESB standards incorporated by reference may be obtained from the North American

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[43] We note the NAESB ACA Certification Program is solely a service offered by NAESB, and is not include in WEQ–012.

[44] Order No. 676–H, FERC Stats. & Regs. ¶ 31,359 at P 71.

[45] Under this process, to be approved a standard must receive a super-majority vote of 67 percent of the members of the WEQ's Executive Committee with support from at least 40 percent from each of the five industry segments—transmission, generation, marketer/brokers, distribution/load serving entities, and end users. For final approval, 67 percent of the WEQ's general membership must ratify the standards.

[46] Public Law 104–113, 12(d), 110 Stat. 775 (1996), 15 U.S.C. 272 note (1997).

[47] 1 CFR 51.5. *See* Incorporation by Reference, 79 FR 66267 (Nov. 7, 2014).

[48] As discussed above, NAESB has also adopted modifications to NERC-related standards, such as WEQ–023, that we do not propose in this NOPR to incorporate by reference.

Energy Standards Board, 801 Travis Street, Suite 1675, Houston, TX 77002, Phone: (713) 356–0060. NAESB's Web site is located at *http://www.naesb.org/.* Copies of the standards may be inspected at the Federal Energy Regulatory Commission, Public Reference and Files Maintenance Branch, 888 First Street NE., Washington, DC 20426, Phone: (202) 502–8371, *http://www.ferc.gov.*[49]

61. NAESB is a private consensus standards developer that develops voluntary wholesale and retail standards related to the energy industry. The procedures used by NAESB make its standards reasonably available to those affected by the Commission regulations, which generally is comprised of entities that have the means to acquire the information they need to effectively participate in Commission proceedings.[50] NAESB provides a free electronic read-only version of the standards for a three business day period or, in the case of a regulatory comment period, through the end of the comment period.[51] Participants can join NAESB, for an annual membership cost of $7,000, which entitles them to full participation in NAESB and enables them to obtain these standards at no additional cost.[52] Non-members may obtain a complete set of Standards Manuals, Booklets, and Contracts on CD for $2,000 and the Individual Standards Manual or Booklets for each standard by email for $250 per manual or booklet.[53] In addition, NAESB considers requests for waivers of the charges on a case by case basis based on need.

V. Information Collection Statement

62. The following collection of information contained in this proposed rule is subject to review by the Office of Management and Budget (OMB) under section 3507(d) of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507(d).[54] OMB's regulations require approval of certain information collection requirements imposed by agency rules.[55] Upon approval of a collection(s) of information, OMB will assign an OMB control number and an expiration date. Respondents subject to the filing requirements of this rule will not be penalized for failing to respond to these collections of information unless the collections of information display a valid OMB control number.

63. The Commission solicits comments on the Commission's need for this information, whether the information will have practical utility, the accuracy of the provided burden estimates, ways to enhance the quality, utility, and clarity of the information to be collected, and any suggested methods for minimizing respondents' burden, including the use of automated information techniques.

64. The following burden estimate is based on the projected costs for the industry to implement the new and revised business practice standards adopted by NAESB and proposed to be incorporated by reference in this NOPR.[56]

REVISIONS IN NOPR IN RM05–5–025

	Number of respondents (1)	Annual number of responses per respondent (2)	Total number of responses (1)*(2)=(3)	Average burden (hours) & cost ($) per response (4)	Total annual burden hours & total annual cost ($) (3)*(4)=(5)
FERC–516E[57][58] (tariff filing)	132	1	132	6 $447	792 hours. $59,004.
FERC–717 (compliance with standards)[59]	132	1	132	30[60] $2,235	3,960 hours. $295,020.
Total	....	....	264	36 hours $2,682	4,752 hours. $354,024.

Costs To Comply With Paperwork Requirements

The estimated annual costs are as follows:

- FERC–516E: 132 entities * 1 response/entity * (6 hours/response * $74.50/hour) = $57,024.
- FERC–717: 132 entities * 1 response/entity * (30 hours/response * $74.50/hour) = $285,120.

Titles: Electric Rate Schedule Filing (FERC–516E); Open Access Same Time Information System and Standards for Business Practices and Communication Protocols for Public Utilities (FERC–717).

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[49] 18 CFR 284.12.

[50] As a private, consensus standards developer, NAESB needs the funds obtained from its membership fees and sales of its standards to finance the organization. The parties affected by these Commission regulations generally are highly sophisticated and have the means to acquire the information they need to effectively participate in Commission proceedings.

[51] Procedures for non-members to evaluate work products before purchasing are available at *https://www.naesb.org/misc/NAESB_Nonmember_Evaluation.pdf. See* Incorporation by Reference, 79 FR at 66271, n.51 & 53 (Nov. 7, 2014) (citing to NAESB's procedure of providing "no-cost, no-print electronic access," NAESB Comment at 1, *http://www.regulations.gov/#!documentDetail;D=OFR-2013-0001-0023*).

[52] North American Energy Standards Board Membership Application, *https://www.naesb.org/pdf4/naesbapp.pdf.*

[53] NAESB Materials Order Form, *https://www.naesb.org//pdf/ordrform.pdf.*

[54] 44 U.S.C. 3507(d).

[55] 5 CFR 1320.11.

[56] Commission staff estimates that industry is similarly situated in terms of hourly cost (wages plus benefits). Based on the Commission average cost (wages plus benefits) for 2016, $74.50/hour is used.

[57] This burden category is intended for "FERC–516," the Commission's identifier that corresponds to OMB Control No. 1902–0096 (Electric Rate Schedules and Tariff Filings). However, another unrelated item is pending OMB review using this OMB Control No. and only one item per OMB Control No. may be pending at a time. Therefore, to ensure timely submission, Commission staff is using FERC–516E (OMB Control No. TBD), a temporary collection number.

[58] These information collection requirements are one-time burden estimates. After implementation in Year 1, the revision proposed in this NOPR would be complete.

[59] "FERC–717" is the Commission's identifier that corresponds to OMB control no. 1902–0173 that identifies the information collection associated with Standards for Business Practices and Communication Protocols for Public Utilities.

[60] The 30-hour estimate was developed in Docket No. RM05–5–013, when the Commission prepared its estimate of the scope of work involved in transitioning to the NAESB Version 002.1 Business Practice Standards. *See* Order No. 676–E, FERC Stats. & Regs. ¶ 31,299 at P 134. We have retained the same estimate here, because the scope of the tasks involved in the transition to Version 003.1 of the Business Practice Standards is very similar to that for the transition to the Version 003 Standards.

Action: Proposed collection.

OMB Control Nos.: TBD (FERC–516E); 1902–0173 (FERC–717).

Respondents: Business or other for profit (Public Utilities—Generally not applicable to small businesses).[61]

Frequency of Responses: One-time implementation (business procedures, capital/start-up).

65. *Necessity of the Information:* This proposed rule, if implemented would upgrade the Commission's current business practice and communication standards and protocols modifications to support compliance with requirements established by the Commission in Order Nos. 890, 890–A, 890–B, and 890–C, as well as modifications to the OASIS-related standards to support Order Nos. 676, 676–A, 676–E, and 717.

66. *Internal Review:* The Commission has reviewed the revised business practice standards and has made a preliminary determination that the proposed revisions that we propose here to incorporate by reference are both necessary and useful. In addition, the Commission has assured itself, by means of its internal review, that there is specific, objective support for the burden estimate associated with the information requirements.

67. Interested persons may obtain information on the reporting requirements by contacting the Federal Energy Regulatory Commission, Office of the Executive Director, 888 First Street NE., Washington, DC 20426 [Attn: Ellen Brown, email: *DataClearance@ferc.gov,* phone: (202) 502–8663, fax: (202) 273–0873].

68. Comments concerning the information collections proposed in this NOPR and the associated burden estimates should be sent to the Commission at this docket and by email to the Office of Management and Budget, Office of Information and Regulatory Affairs [Attention: Desk Officer for the Federal Energy Regulatory Commission]. For security reasons, comments should be sent by email to OMB at the following email address: *oira_submission@omb.eop.gov.* Please reference the docket number of this Notice of Proposed Rulemaking (Docket No. RM05–5–25) and OMB Control Nos. TBD (FERC–516E) and 1902–0173 (FERC–717) in your submission.

VI. Environmental Analysis

69. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[62] The Commission has categorically excluded certain actions from these requirements as not having a significant effect on the human environment.[63] The actions proposed here fall within categorical exclusions in the Commission's regulations for rules that are clarifying, corrective, or procedural, for information gathering, analysis, and dissemination, and for sales, exchange, and transportation of electric power that requires no construction of facilities.[64] Therefore, an environmental assessment is unnecessary and has not been prepared in this NOPR.

VII. Regulatory Flexibility Act Certification

70. The Regulatory Flexibility Act of 1980 (RFA)[65] generally requires a description and analysis of proposed rules that will have significant economic impact on a substantial number of small entities. The RFA does not mandate any particular outcome in a rulemaking. It only requires consideration of alternatives that are less burdensome to small entities and an agency explanation of why alternatives were rejected.

71. The Small Business Administration (SBA) revised its size standards (effective January 22, 2014) for electric utilities from a standard based on megawatt hours to a standard based on the number of employees, including affiliates. Under SBA's standards, some transmission owners will fall under the following category and associated size threshold: Electric bulk power transmission and control, at 500 employees.[66]

72. The Commission estimates that 5 of the 132 respondents are small. The Commission estimates that the impact on these entities is consistent with the paperwork burden of $2,682 per entity used above.[67] The Commission does not consider $2,682 to be a significant economic impact.

73. Based on the above, the Commission certifies that implementation of the proposed Business Practice Standards will not have a significant impact on a substantial number of small entities. Accordingly, no initial regulatory flexibility analysis is required.

VIII. Comment Procedures

74. The Commission invites interested persons to submit comments on the matters and issues proposed in this notice to be adopted, including any related matters or alternative proposals that commenters may wish to discuss. Comments are due September 26, 2016. Comments must refer to Docket No. RM05–5–025 and must include the commenter's name, the organization they represent, if applicable, and their address in their comments.

75. The Commission encourages comments to be filed electronically via the eFiling link on the Commission's Web site at *http://www.ferc.gov.* The Commission accepts most standard word processing formats. Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format. Commenters filing electronically do not need to make a paper filing.

76. Commenters that are not able to file comments electronically must send an original of their comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

77. All comments will be placed in the Commission's public files and may be viewed, printed, or downloaded remotely as described in the Document Availability section below. Commenters on this proposal are not required to serve copies of their comments on other commenters.

IX. Document Availability

78. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through the Commission's Home Page (*http://www.ferc.gov*) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE., Room 2A, Washington, DC 20426.

79. From the Commission's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

80. User assistance is available for eLibrary and the Commission's Web site during normal business hours from the

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[61] *See infra* PP 72–73.

[62] *Regulations Implementing the National Environmental Policy Act of 1969,* Order No. 486, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs., Regulations Preambles 1986–1990 ¶ 30,783 (1987).

[63] 18 CFR 380.4.

[64] *See* 18 CFR 380.4(a)(2)(ii), 380.4(a)(5), 380.4(a)(27).

[65] 5 U.S.C. 601–612.

[66] 13 CFR 121.201, Sector 22 (Utilities), NAICS code 221121 (Electric Bulk Power Transmission and Control).

[67] 36 hours at $74.50/hour = $2,682.

Commission's Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

List of Subjects

18 CFR Part 2

Electric utilities, Guidance and policy statements.

18 CFR Part 38

Conflict of interests, Electric power plants, Electric utilities, Incorporation by reference, Reporting and recordkeeping requirements.

By direction of the Commission.

Dated: July 21, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

In consideration of the foregoing, the Commission proposes to amend parts 2 and 38, chapter I, title 18, Code of Federal Regulations, as follows:

PART 2—GENERAL POLICY AND INTERPRETATIONS

■ 1. The authority citation for part 2 continues to read as follows:

Authority: 5 U.S.C. 601; 15 U.S.C. 717–717z, 3301–3432, 16 U.S.C. 792–828c, 2601–2645; 42 U.S.C. 4321–4370h, 7101–7352.

■ 2. Amend § 2.27 by revising paragraph (d) to read as follows:

§ 2.27 Availability of North American Energy Standards Board (NAESB) Smart Grid Standards as non-mandatory guidance.

* * * * *

(d) WEQ–019, Customer Energy Usage Information Communication (WEQ Version 003.1, Sep. 30, 2015); and

* * * * *

PART 38—STANDARDS FOR PUBLIC UTILITY BUSINESS OPERATIONS AND COMMUNICATIONS

■ 3. The authority citation for part 38 continues to read as follows:

Authority: 16 U.S.C. 791–825r, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352.

■ 4. Amend § 38.1, by revising paragraph (b) to read as follows:

§ 38.1 Incorporation by reference of North American Energy Standards Board Wholesale Electric Quadrant standards.

* * * * *

(b) The business practice and electronic communication standards the Commission incorporates by reference are as follows:

(1) WEQ–000, Abbreviations, Acronyms, and Definition of Terms (Version 003.1, Sep., 30, 2015);

(2) WEQ–001, Open Access Same-Time Information System (OASIS), OASIS Version 2.1 (WEQ Version 003.1, Sep. 30, 2015) with the exception of Standards 001–9.5, 001–10.5, 001–14.1.3, 001–15.1.2 and 001–106.2.5);

(3) WEQ–002, Open Access Same-Time Information System (OASIS) Business Practice Standards and Communication Protocols (S&CP), OASIS Version 2.1 (WEQ Version 003.1, Sep. 30, 2015);

(4) WEQ–003, Open Access Same-Time Information System (OASIS) Data Dictionary Business Practice Standards, OASIS Version 2.1 (WEQ Version 003.1, Sep. 30, 2015);

(5) WEQ–004, Coordinate Interchange (WEQ Version 003.1, Sep. 30, 2015);

(6) WEQ–005, Area Control Error (ACE) Equation Special Cases (WEQ Version 003.1, Sep. 30, 2015);

(7) WEQ–006, Manual Time Error Correction (WEQ Version 003, Sep. 30, 2015);

(8) WEQ–007, Inadvertent Interchange Payback (WEQ Version 003.1, Sep. 30, 2015);

(9) WEQ–008, Transmission Loading Relief (TLR)—Eastern Interconnection (WEQ Version 003.1, Sep. 30, 2015);

(10) WEQ–011, Gas/Electric Coordination (WEQ Version 003.1, Sep. 30, 2015);

(11) WEQ–012, Public Key Infrastructure (PKI) (WEQ Version 003.1, Sep. 30, 2015);

(12) WEQ–013, Open Access Same-Time Information System (OASIS) Implementation Guide, OASIS Version 2.1 (WEQ Version 003.1, Sep. 30, 2015);

(13) WEQ–015, Measurement and Verification of Wholesale Electricity Demand Response (WEQ Version 003.1, Sep. 30, 2015);

(14) WEQ–021, Measurement and Verification of Energy Efficiency Products (WEQ Version 003.1, Sep. 30, 2015).

(15) WEQ–022, Electric Industry Registry Business Practice Standards (WEQ Version 003.1, Sep. 30, 2015); and

(16) WEQ–023, Modeling Business Practice Standards (WEQ Version 003.1, Sep. 30, 2015).

[FR Doc. 2016–17841 Filed 7–27–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 35

[Docket No. RM15–23–000]

Collection of Connected Entity Data From Regional Transmission Organizations and Independent System Operators; Withdrawal

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Withdrawal of notice of proposed rulemaking and termination of rulemaking proceeding.

SUMMARY: The Federal Energy Regulatory Commission (Commission) is withdrawing its proposal to amend its regulations to require each regional transmission organization and independent system operator to electronically deliver to the Commission, on an ongoing basis, data required from its market participants that would: Identify the market participants by means of a common alpha-numeric identifier; list their "Connected Entities;" and describe in brief the nature of the relationship of each Connected Entity. The Commission is also concurrently issuing a Notice of Proposed Rulemaking in Docket No. RM16–17–000, which supersedes this proposal.

DATES: The notice of proposed rulemaking published on September 29, 2015, at 80 FR 58382, is withdrawn as of July 28, 2016.

FOR FURTHER INFORMATION CONTACT: Jamie Marcos, Office of Enforcement, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–6628, *Jamie.marcos@ferc.gov.*

SUPPLEMENTARY INFORMATION:

1. On September 17, 2015, the Commission issued a Notice of Proposed Rulemaking (NOPR) in this proceeding.[1] For the reasons set forth below, we are exercising our discretion to withdraw the NOPR and terminate this rulemaking proceeding. The NOPR is superseded by the new proposal reflected in the concurrently issued NOPR on Data Collection for Analytics and Surveillance and Market-Based Rate Purposes (Data Collection NOPR).[2]

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[1] *Collection of Connected Entity Data from Regional Transmission Organizations and Independent System Operators,* FERC Stats. & Regs. ¶ 32,711 (2015).

[2] *Data Collection for Analytics and Surveillance and Market-Based Rate Purposes,* 156 FERC ¶ 61,045 (2016).

2. In the NOPR, the Commission proposed to amend its regulations to require each regional transmission organization and independent system operator to electronically deliver to the Commission, on an ongoing basis, data required from its market participants that would: (i) Identify the market participants by means of a common alpha-numeric identifier; (ii) list their "Connected Entities," which included entities that have certain ownership, employment, debt, or contractual relationships with the market participants; and (iii) describe in brief the nature of the relationship of each Connected Entity. The Commission proposed to collect such information to assist with its screening and investigative efforts to detect market manipulation. The Commission has since developed a new proposal, as reflected in the concurrently issued Data Collection NOPR, which is substantially narrower than the proposal in the instant NOPR, and streamlines and consolidates the collection of market-based rate information with new information proposed to be collected for analytics and surveillance purposes. Among other things, in the Data Collection NOPR, the Commission proposes to require market-based rate sellers and certain market participants in Commission-jurisdictional organized electric markets to submit certain, defined information about their financial and legal connections to other entities. While the Data Collection NOPR proposes to collect similar information to that which was proposed in the NOPR in this proceeding, this new proposal presents substantial revisions, thereby superseding the proposal in the instant NOPR.

3. The Commission therefore withdraws the NOPR and terminates this rulemaking proceeding.

By direction of the Commission.

Dated: July 21, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–17853 Filed 7–27–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 35

[Docket No. RM16–3–000]

Ownership Information in Market-Based Rate Filings; Withdrawal

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Withdrawal of notice of proposed rulemaking and termination of rulemaking proceeding.

SUMMARY: The Federal Energy Regulatory Commission (Commission) is withdrawing its proposal to amend its regulations to clarify the scope of ownership information that sellers seeking to obtain or retain market-based rate authority must provide. The Commission is also concurrently issuing a Notice of Proposed Rulemaking in Docket No. RM16–17–000, which supersedes this proposal.

DATES: The notice of proposed rulemaking published on December 24, 2015, at 80 FR 80302, is withdrawn as of July 28, 2016.

FOR FURTHER INFORMATION CONTACT:

Ashley Dougherty (Technical Information), Office of Energy Market Regulation, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–8851, *ashley.dougherty@ferc.gov.*

Laura Chipkin (Legal Information), Office of General Counsel, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–8615, *laura.chipkin@ferc.gov.*

SUPPLEMENTARY INFORMATION:

1. On December 17, 2015, the Commission issued a Notice of Proposed Rulemaking (NOPR) in this proceeding.[1] For the reasons set forth below, we are exercising our discretion to withdraw the NOPR and terminate this rulemaking proceeding.

2. In the NOPR, the Commission proposed to amend its regulations to clarify the scope of ownership information that sellers seeking to obtain or retain market-based rate authority must provide. The Commission has since developed a new proposal, as reflected in a concurrently issued NOPR (Data Collection NOPR),[2] to streamline and consolidate the collection of market-based rate (MBR) information with new information proposed to be collected for analytics and surveillance purposes. Among other things, in the Data Collection NOPR, the Commission proposes to change certain aspects of the substance and format of information submitted for MBR purposes, thereby superseding the proposed clarifications in the instant NOPR.

3. The Commission therefore withdraws the NOPR and terminates this rulemaking proceeding.

By the Commission.

Issued: July 21, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–17856 Filed 7–27–16; 8:45 am]

BILLING CODE 6717–01–P

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[1] *Ownership Information in Market-Based Rate Filings,* FERC Stats & Regs. ¶ 32,713 (2015).

[2] *Data Collection for Analytics and Surveillance and Market-Based Rate Purposes,* 156 FERC ¶ 61,045 (2016).

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 33

[EPA–HQ–OA–2006–0278; FRL–9946–26–OA]

RIN 2090–AA40

Participation by Disadvantaged Business Enterprises in Procurements Under EPA Financial Assistance Agreements

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: Environmental Protection Agency (EPA) is proposing to amend the Disadvantaged Business Enterprise (DBE) program. These proposed amendments will improve the practical utility of the program, minimize burden, and clarify requirements that have been the subject of questions from recipients of EPA financial assistance and from disadvantaged business enterprises. These revisions are in accordance with the requirements of the Federal laws that govern the EPA DBE program.

DATES: Comments must be received on or before August 29, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OA–2006–0278, at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Teree Henderson, Office of the Administrator, Office of Small Business Programs (mail code: 1230A), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: 202–566–2222; fax number: 202–566–0548; email address: *henderson.teree@epa.gov.*

SUPPLEMENTARY INFORMATION:

Why is EPA issuing this proposed rule?

The Agency has published a direct final rule in the "Rules and Regulations" section of this **Federal Register**, approving the DBE program revisions, because EPA views the revisions as noncontroversial and anticipates no adverse comment. The Agency provided reasons for the approval and additional supplementary information in the preamble to the direct final rule. If EPA receives no adverse comment, the Agency will not take further action on this proposed rule. If EPA receives adverse comment, the Agency will withdraw the direct final rule and it will not take effect. The EPA would then address all public comments in any subsequent final rule based on this proposed rule. The EPA does not intend to institute a second comment period on this action.

Any parties interested in commenting must do so at this time. For further information, please contact the persons in the **FOR FURTHER INFORMATION CONTACT** section of this document.

List of Subjects in 40 CFR Part 33

Environmental protection, Grant programs.

Dated: July 15, 2016.

Gina McCarthy,

Administrator.

[FR Doc. 2016–17509 Filed 7–27–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2013–0004: FRL–9949–69–Region 10]

Partial Approval and Partial Disapproval of Attainment Plan for Oakridge, Oregon PM$_{2.5}$ Nonattainment Area

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: On December 12, 2012, the Oregon Department of Environmental Quality (ODEQ) submitted, on behalf of the Governor of Oregon, a State Implementation Plan (SIP) submission to address violations of the National Ambient Air Quality Standards (NAAQS) for particulate matter with an aerodynamic diameter of less than or equal to a nominal 2.5 micrometers in diameter (PM$_{2.5}$) for the Oakridge PM$_{2.5}$ nonattainment area (2012 SIP submission). The Lane Regional Air Protection Agency (LRAPA) in coordination with ODEQ developed the 2012 SIP submission for purposes of attaining the 2006 24-hour PM$_{2.5}$ NAAQS. On February 22, 2016, the ODEQ withdrew certain provisions of the 2012 SIP submission (2016 SIP withdrawal). The Environmental Protection Agency (EPA) has evaluated whether the remaining portions of the Oakridge 2012 SIP submission meet the applicable Clean Air Act (CAA) requirements. Based on this evaluation, the EPA is proposing to partially approve and partially disapprove the remaining portions of the 2012 SIP submission.

DATES: Comments must be received on or before August 29, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R10–OAR–2013–0004 at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

Docket: All documents in the electronic docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information that is restricted by statute from disclosure. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available at *http://www.regulations.gov* or at EPA Region 10, Office of Air and Waste, 1200 Sixth Avenue, Seattle, Washington 98101. The EPA requests that you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Christi Duboiski at (360) 753–9081, *duboiski.christi@epa.gov,* or the above EPA, Region 10 address.

SUPPLEMENTARY INFORMATION: Throughout this document, wherever "we", "us" or "our" are used, it is intended to refer to the EPA.

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I. Background for the EPA's Proposed Action

A. History of the PM$_{2.5}$ NAAQS

On July 18, 1997, the EPA promulgated the 1997 PM$_{2.5}$ NAAQS, including annual standards of 15.0 µg/m^3 based on a 3-year average of annual mean PM$_{2.5}$ concentrations, and 24-hour (or daily) standards of 65 µg/m^3 based on a 3-year average of the 98th percentile of 24-hour concentrations (62 FR 38652). The EPA established the

1997 $PM_{2.5}$ NAAQS based on significant evidence and numerous health studies demonstrating the serious health effects associated with exposures to $PM_{2.5}$. To provide guidance on the CAA requirements for state and tribal implementation plans to implement the 1997 $PM_{2.5}$ NAAQS, the EPA promulgated the "Final Clean Air Fine Particle Implementation Rule" (72 FR 20586, April 25, 2007) (hereinafter, the "2007 $PM_{2.5}$ Implementation Rule").

On October 17, 2006, the EPA strengthened the 24-hour $PM_{2.5}$ NAAQS to 35 $\mu g/m^3$ and retained the level of the annual $PM_{2.5}$ standard at 15.0 $\mu g/m^3$ (71 FR 61144). Following promulgation of a new or revised NAAQS, the EPA is required by the CAA to promulgate designations for areas throughout the United States; this designation process is described in section 107(d)(1) of the CAA. On November 13, 2009, the EPA designated areas across the United States with respect to the revised 2006 24-hour $PM_{2.5}$ NAAQS (74 FR 58688). In that November 2009 action, the EPA designated Oakridge, Oregon, and a small surrounding area as nonattainment for the 2006 24-hour $PM_{2.5}$ NAAQS (Oakridge NAA), requiring Oregon to prepare and submit to the EPA an attainment plan for the Oakridge NAA to meet the 2006 24-hour $PM_{2.5}$ NAAQS. On March 2, 2012, the EPA issued "Implementation Guidance for the 2006 24-Hour Fine Particulate ($PM_{2.5}$) National Ambient Air Quality Standards (NAAQS)" to provide guidance on the development of SIPs to demonstrate attainment with the 24-hour standards (March 2012 Implementation Guidance). The March 2012 Implementation Guidance explained that the overall framework and policy approach of the 2007 $PM_{2.5}$ Implementation Rule provided effective and appropriate guidance on statutory requirements for the development of SIPs to attain the 2006 24-hour $PM_{2.5}$ NAAQS. Accordingly, the March 2012 Implementation Guidance instructed states to rely on the 2007 $PM_{2.5}$ Implementation Rule in developing SIPs to demonstrate attainment with the 2006 24-hour $PM_{2.5}$ NAAQS.

B. January 4, 2013 D.C. Circuit Court Decision Regarding $PM_{2.5}$ Implementation Under Subpart 4

On January 4, 2013, the D.C. Circuit Court issued a decision in *Natural Resources Defense Council* v. *EPA*, 706 F.3d 428, holding that the EPA erred in implementing the 1997 $PM_{2.5}$ NAAQS pursuant to the general implementation provisions of subpart 1 of Part D of Title I of the CAA (subpart 1), rather than the particulate-matter-specific provisions of subpart 4 of Part D of Title I (subpart 4). The Court did not vacate the 2007 $PM_{2.5}$ Implementation Rule but remanded the rule with instructions for the EPA to promulgate new implementation regulations for the $PM_{2.5}$ NAAQS in accordance with the requirements of subpart 4. On June 6, 2013, consistent with the Court's remand decision, the EPA withdrew its March 2012 Implementation Guidance which relied on the 2007 $PM_{2.5}$ Implementation Rule to provide guidance for the 2006 24-hour $PM_{2.5}$ NAAQS.

Prior to the January 4, 2013 *NRDC* decision, states had worked towards meeting the air quality goals of the 2006 $PM_{2.5}$ NAAQS in accordance with the EPA regulations and guidance derived from subpart 1 of Part D of Title I of the CAA. The EPA considered this history in issuing the $PM_{2.5}$ Subpart 4 Nonattainment Classification and Deadline Rule (79 FR 31566, June 2, 2014) that identified the initial classification under subpart 4 for areas currently designated nonattainment for the 1997 and/or 2006 $PM_{2.5}$ NAAQS as "moderate" nonattainment areas. The final rule also established December 31, 2014 as the new deadline for the states to submit any additional SIP submissions related to attainment for the 1997 or 2006 $PM_{2.5}$ NAAQS.

The ODEQ submitted an attainment plan for the Oakridge NAA on December 12, 2012. The plan included measures intended to demonstrate attainment of the 2006 $PM_{2.5}$ NAAQS by December 31, 2014. In this notice the EPA evaluates the State's existing attainment plan submission for the 2006 $PM_{2.5}$ NAAQS to determine whether it meets the applicable statutory requirements. The applicable statutory requirements include not only the applicable requirements of subpart 1, but also the applicable requirements of subpart 4. This interpretation is consistent with the *NRDC* Court's decision that the EPA must implement the $PM_{2.5}$ NAAQS consistent with the requirements of subpart 4.

C. CAA $PM_{2.5}$ Moderate Area Nonattainment SIP Requirements

With respect to the requirements for attainment plans for the $PM_{2.5}$ NAAQS, the EPA notes that the general nonattainment area planning requirements are found in subpart 1, and the moderate area planning requirements specifically for particulate matter are found in subpart 4. The EPA has a longstanding general guidance document that interprets the 1990 amendments to the CAA commonly referred to as the "General Preamble" (57 FR 13498, April 16, 1992). The General Preamble addresses the relationship between subpart 1 and subpart 4 requirements and provides recommendations to states for meeting statutory requirements for particulate matter attainment planning. Specifically, the General Preamble explains that requirements applicable to moderate area attainment plan SIP submissions are set forth in subpart 4, but such SIP submissions must also meet the general attainment planning provisions in subpart 1, to the extent these provisions "are not otherwise subsumed by, or integrally related to," the more specific subpart 4 requirements (57 FR 13538). Additionally, the EPA proposed the *Fine Particulate Matter National Ambient Air Quality Standards: State Implementation Plan Requirements* rule (80 FR 15340, March 23, 2015), to clarify our interpretations of the statutory requirements that apply to moderate and serious $PM_{2.5}$ nonattainment areas (NAAs) under subparts 1 and 4.

The CAA requirements of subpart 1 for attainment plans include: (i) The section 172(c)(1) requirements for reasonably available control measures (RACM), reasonably available control technology (RACT) and attainment demonstrations; (ii) the section 172(c)(2) requirement to demonstrate reasonable further progress (RFP); (iii) the section 172(c)(3) requirement for emissions inventories; (iv) the section 172(c)(5) requirements for a nonattainment new source review (NSR) permitting program; and (v) the section 172(c)(9) requirement for contingency measures.

The CAA subpart 4 requirements for moderate areas are generally comparable with the subpart 1 requirements and include: (i) The section 189(a)(1)(A) NSR permit program requirements; (ii) the section 189(a)(1)(B) requirements for attainment demonstration; (iii) the section 189(a)(1)(C) requirements for RACM; and (iv) the section 189(c) requirements for RFP and quantitative milestones. In addition, under subpart 4 the moderate area attainment date is as expeditiously as practicable but no later than the end of the 6th calendar year after designation.

II. Content of 2012 SIP Submission and the EPA's Evaluation

The LRAPA, in coordination with ODEQ, developed the 2012 SIP submission for the Oakridge NAA that was subsequently adopted by the State and submitted by the ODEQ to the EPA. The following describes the relevant contents of the 2012 SIP submission, the 2016 SIP withdrawal, and the EPA's evaluation of the remaining SIP provisions.

The 2012 SIP submission included provisions that address the requirements of an attainment plan for a moderate $PM_{2.5}$ nonattainment area including RACT/RACM, emissions inventories, modeling, attainment demonstration, transportation conformity and motor vehicle emissions budgets, RFP and contingency measures.

The 2016 SIP withdrawal included the State's withdrawal of the following 2012 SIP submission provisions:

- OAR 340–200–0040—General Air Pollution Procedures and Definitions; the adopted and amended version of the rules and Redline/strikeout version of the adopted and amended rules.
- The LRAPA's Title 29—Designation of Air Quality Areas; the adopted and amended version of the rules and redline/strikeout version of the adopted and amended rules *except:*
  - ○ 29–0010(10)—Oakridge $PM_{2.5}$ Nonattainment Area definition
  - ○ 29–0030 Designation of Nonattainment Areas
- Title 38—Major New Source Review
- Smoke Management Directive

The state withdrew OAR–340–200–0040, portions of the LRAPA Title 29, Title 38 and the Smoke Management Directive because they were not intended to be included in the SIP submission.

State Nonattainment Area Description and Designation

The 2012 SIP submission contained revised portions of the LRAPA Title 29, "Designation of Air Quality Areas" (29–0010(10) and 29–0030) adopted on October 18, 2012 that identify and describe the Oakridge $PM_{2.5}$ area and lists the Oakridge $PM_{2.5}$ area as nonattainment. The area described as the Oakridge $PM_{2.5}$ nonattainment area in the LRAPA Title 29 is consistent with the federal nonattainment area designated at 40 CFR 81.338. We propose to approve the State's area description and listing as nonattainment.

Emissions Inventory

Section 172(c)(3) of the CAA requires the development of emissions inventories for nonattainment areas. In addition, the planning and associated modeling requirements set forth in CAA section 189(a) make the development of an accurate and up-to-date emissions inventory a critical element of any viable attainment plan. EPA guidance specifies the best practices for developing emission inventories for $PM_{2.5}$ nonattainment areas (see "Emissions Inventory Guidance for Implementation of Ozone and Particulate Matter National Ambient Air Quality Standards (NAAQS) and Regional Haze Regulations"). The 2012 SIP submission contains planning inventories of emission sources and emission rates for the base year of 2008 and the projected attainment year of 2014. The LRAPA chose the year 2008 as the base year because it is one of the three years used to designate the area as nonattainment as well as the middle year of the five year period, 2006–2010, used for the determining the base year design value. Additionally, the LRAPA determined that high-quality emission information was already available from the National Emission Inventory for 2008. The LRAPA developed the base year emissions inventory for the nonattainment area. Table 1 provides information on the worst case winter season day, most relevant to attainment planning, as well as the typical winter season day. Annual emissions for primary $PM_{2.5}$, NO_X, SO_2, VOC, and NH_3 can be found in the docket in the LRAPA's SIP submission. The LRAPA determined the precursor emissions for a typical winter day accounted for less than 6 percent of the total PM. The 2012 SIP submission listed total emissions of direct $PM_{2.5}$ on a typical winter day at 525 pounds per day (lbs/day). The source categories contributing to the typical winter day total were identified as follows: Area sources, primarily RWC, emit 479 pounds per day (lbs/day); mobile sources, including railroads and re-entrained road dust emit 44.7 lbs/day; and permitted stationary sources emit 0.5 lbs/day.

TABLE 1—2008 OAKRIDGE; TYPICAL SEASON DAY AND WORST-CASE DAY $PM_{2.5}$ EMISSIONS

[lbs/day]

Source sector	$PM_{2.5}$ lbs/per day	
	Typical season day	Worst case day
Permitted Point	0.5	0.9
Stationary Area	479.5	480
Onroad	38.7	65.1
Nonroad	6.0	6.0
Total	525	552

The EPA has reviewed the base year emission inventory and believes it satisfies the CAA section 172(c)(3) requirement for a comprehensive, accurate and current inventory of actual 2008 emissions of the relevant pollutants in the Oakridge NAA. Thus, the EPA proposes to approve the base year emission inventory in the 2012 SIP submittal.

2014 Projected Attainment Inventory for the Nonattainment Area

The 2012 SIP submittal included a projected 2014 attainment year emissions inventory that supported attainment by December 2014. The 2014 attainment year emissions inventory included the same source categories as the 2008 base year. Emissions in the 2014 attainment year inventory were adjusted to account for emissions increases due to anticipated growth between 2008 and 2014 and emissions decreases from implementation of the control strategies identified in the RACM analysis.

Due to the fact that the Oakridge NAA failed to attain the $PM_{2.5}$ NAAQS by the December 31, 2014 attainment date projected in the 2012 SIP submission, the EPA presumes that the attainment year emission inventory was not accurate. The quality-assured and certified ambient air monitoring data from the Willamette Activity Center monitoring site from 2012 through 2014, yields a design value of 40 µg/m³ and confirms that the area did not attain the 2006 24-hour $PM_{2.5}$ NAAQS by December 31, 2014. Thus, the EPA proposes to disapprove the projected 2014 attainment year inventory in the 2012 SIP submission.

Federal Requirement for RACM, Including RACT

The general SIP planning requirements for nonattainment areas under subpart 1 include section 172(c)(1), which requires implementation of all RACM (including RACT). The language of section 172(c) requires that attainment plans provide for the implementation of RACM (including RACT) to provide for attainment of the NAAQS. Therefore, what constitutes RACM and RACT is related to what is necessary for attainment in a given area.

Subpart 4 also requires states to develop attainment plans that evaluate potential control measures and impose RACM and RACT on sources within a moderate nonattainment area that are necessary to expeditiously attain the NAAQS. Section 189(a)(1)(C) requires that moderate nonattainment plans provide for implementation of RACM and RACT no later than four years after the area is designated as nonattainment. As with subpart 1, the terms RACM and RACT are not defined within subpart 4. Nor do the provisions of subpart 4 specify how states are to meet the RACM and RACT requirements. However, the EPA's longstanding guidance in the General Preamble provides recommendations for determining which control measures constitute RACM and RACT for purposes of meeting the statutory requirements of subpart 4. 57 FR 13540–41.

For both RACM and RACT, the EPA notes that an overarching principle is that if a given control measure is not needed to attain the relevant NAAQS in a given area as expeditiously as practicable, then that control measure would not be required as RACM or RACT because it would not be reasonable to impose controls that are not in fact needed for attainment purposes. Accordingly, a RACM and RACT analysis is a process to identify emissions sources, evaluate potential emissions controls, and impose those control measures and technologies that are reasonable and necessary to bring the area into attainment as expeditiously as practicable, but by no later than the applicable attainment date for the area. However, the EPA has long-applied a policy that states evaluate the combined effect of reasonably available control measures that were not necessary to demonstrate attainment by the statutory attainment, and if they collectively advance the attainment date by at least one-year the measures should be adopted to satisfy the statutory requirement that attainment be as expeditious as practicable (80 FR 15369).

Identification of RACM and RACT

The LRAPA provided a RACM and RACT analysis in Appendix J of the 2012 SIP submission. The submission explained that residential wood combustion (RWC) sources (*e.g.*, woodstoves, fireplaces, pellet stoves) account for 86% of emissions on worst-case winter days when exceedance of the NAAQS is most likely to occur. The other contributing sources were identified as road dust (5%), transportation (7.9%) and industrial and other unidentified area sources (1.1%). The LRAPA also conducted a speciation analysis, included in Appendix E of the 2012 SIP submission, which demonstrated that 96% of total particulate matter is from organic and elemental carbon, with significantly smaller amounts of secondary inorganic aerosols including nitrate (0.4%), sulfate (1%) and ammonium (.03%). Based on these and other analyses, the LRAPA concluded that RWC was the major contributor to $PM_{2.5}$ concentrations on worst-case winter days and focused its RACM analysis on this source category.

Emissions from RWC for winter home heating has been a long-standing air pollution problem for the Oakridge NAA, first identified when EPA designated the area nonattainment for the PM_{10} NAAQS. The Oakridge nonattainment area PM_{10} SIP adopted a control strategy that specifically addressed emissions from RWC (64 FR 12751). In the 2012 SIP submission for the 2006 $PM_{2.5}$ NAAQS, the LRAPA likewise focused on RWC emissions and described a suite of control measures that included measures in effect from the previous approved PM_{10} attainment plan as well as new measures specifically intended to address $PM_{2.5}$. While the LRAPA described several control measures in the 2012 $PM_{2.5}$ SIP submission, it only relied on emission reductions from measures implemented after the base year of 2008. These measures are:

- RWC curtailment during adverse meteorological conditions and air quality advisories are issued: Oakridge City ordinance 889;
- Motor vehicle emission reductions due to federal emissions requirements; and,
- Woodstove change outs of uncertified stoves to EPA certified stoves since 2008.

In its RACT analysis, the LRAPA identified two industrial stationary sources in the nonattainment area, a rock crusher and ready-mix concrete plant, which are described as minor sources of direct and precursor emissions for purposes of $PM_{2.5}$. The LRAPA asserts that these two small sources together emit less than one ton per year of $PM_{2.5}$ emissions and contribute less than 1% to the 2008 base year emission inventory. The EPA National Emission Inventory data for the Oakridge NAA as presented in Appendix D of the 2012 SIP submission (attachment 3.3d, pages 207–210) identified precursor emissions for the base year of 2008. That data show there are no precursor emissions from industrial sources in the Oakridge NAA.

In the 2012 SIP submission, the LRAPA reviewed the two stationary sources and determined that the air pollution control technology installed on these sources are the current standard for the industry. The rock crusher controls emissions of $PM_{2.5}$ using water spray. The concrete batch plant uses baghouse controls to reduce $PM_{2.5}$ emissions. The SIP submission did not propose or contain any additional control technologies for purposes of meeting RACT based on the existing particulate matter control measures and the minimal contribution to $PM_{2.5}$ concentrations from the two small stationary sources. Operating permits for these two sources were not included in the 2012 SIP submission.

The EPA's Evaluation of RACM Including RACT

The measures selected and implemented by the LRAPA to meet RACM including RACT requirements did not provide for attainment of the $PM_{2.5}$ NAAQS by the attainment date in the 2012 SIP submission of December 31, 2014. In addition, the RWC curtailment program included in the 2012 SIP submission, identified as Oakridge City Ordinance 889, was rescinded and is no longer in effect. A new replacement ordinance, Oakridge City Ordinance 914 has not yet been submitted to EPA for incorporation into the SIP. Based on the foregoing, the suite of control measures in the 2012 SIP submission do not represent RACM and RACT and fail to meet the requirements of section 172(c)(1) and section 189(a)(1)(C) of the CAA. Accordingly, we are proposing to disapprove the RACM and RACT provisions of the 2012 SIP submission.

Attainment Demonstration and Modeling

Section 189(a)(1)(B) requires that a $PM_{2.5}$ moderate area SIP contain either a demonstration that the plan will provide for attainment by the applicable attainment date, or a demonstration that attainment by such date is impracticable. In the attainment demonstration of the 2012 SIP submission, the LRAPA described how the attainment plan would provide the emissions reductions needed to bring the Oakridge NAA into attainment with the 2006 24-hour $PM_{2.5}$ NAAQS no later than December 31, 2014.

All attainment demonstrations must project air quality below the standard using air quality modeling. The ODEQ submitted a modeled demonstration that is consistent with the recommendations contained in the EPA's modeling guidance document "Guidance on the Use of Models and Other Analyses for Demonstrating Attainment of Air Quality Goals for Ozone, $PM_{2.5}$, and Regional Haze" (EPA–454/B–07–002, April 2007) and the June 28, 2011, memorandum from Tyler Fox to Regional Air Program Managers, "Update to the 24-hour $PM_{2.5}$ Modeled Attainment Test." States should base modeling on national (*e.g.*, EPA), regional (*e.g.*, Western Regional Air Partnership) or local modeling, or a combination thereof, if appropriate. The April 2007 guidance indicates that states should review supplemental analyses, in combination with the modeling analysis, in a "weight of evidence" assessment to determine whether each area is likely to achieve timely attainment.

The LRAPA used a proportional "roll-forward" model to project air quality levels into the future. The linear model the LRAPA used for the Oakridge NAA considered the concentrations of individual chemical species analyzed from the $PM_{2.5}$ filters. The model does not account for secondary chemistry because inert species comprise more than 97% of the total $PM_{2.5}$ in the Oakridge NAA. The EPA believes that the roll-forward model is an appropriate approach for the Oakridge NAA due to the limited number of emission sources and source categories, the limited contribution of secondary aerosol, and the even dispersal of emission sources across the area. The LRAPA determined the emission changes of each species from the base year to a future attainment year based on emissions growth or emissions reduction from trends in technology and population, and considering both national control measures (such as Tier 2 gasoline vehicle standards), and control measures included as part of the SIP submission. These emission changes and resulting changes in ambient chemical species levels were summed to estimate future year projected $PM_{2.5}$ concentrations.

The attainment demonstration starts with estimating the baseline design value for $PM_{2.5}$. The procedure for its calculation is presented in Appendix N to 40 CFR 50, "Interpretation of the National Ambient Air Quality Standards for Particulate Matter," EPA Guidance on the Use of Models and Other Analyses for Demonstrating Attainment of Air Quality Goals for O3, $PM_{2.5}$, and Regional Haze," and the June 28, 2011, memorandum from Tyler Fox to Regional Air Program Managers, "Update to the 24-hour $PM_{2.5}$ Modeled Attainment Test." Ambient $PM_{2.5}$ concentrations from 2006 to 2010 were used to calculate a baseline design value of 39.5 $\mu g/m^3$. Detailed methods on the baseline design value calculation are in Appendix G of the 2012 SIP submission.

Quality-assured and certified ambient air monitoring data from the Willamette Activity Center monitoring site from 2012 through 2014, yields a design value of 40 $\mu g/m^3$ and confirms that the area did not attain the 2006 24-hour $PM_{2.5}$ NAAQS by December 31, 2014. Therefore, EPA is proposing to disapprove the attainment demonstration portion of the 2012 SIP submission because the area failed to attain by the projected attainment date.

Reasonable Further Progress and Quantitative Milestones

For $PM_{2.5}$ nonattainment areas, two statutory provisions apply regarding RFP and quantitative milestones. First, under subpart 1, CAA section 172(c)(2) requires attainment plans to provide for RFP, which is defined in CAA section 171(l) as "such annual incremental reductions in emissions of the relevant air pollutant as are required by [Part D of Title I] or may reasonably be required by the Administrator for the purpose of ensuring attainment of the applicable national ambient air quality standard by the applicable date." Reasonable further progress is a requirement to assure that states make steady, incremental progress toward attaining air quality standards, rather than deferring implementation of control measures and thereby emission reductions until before the date by which the standard is to be attained. Second, CAA section 189(c) requires that attainment plans for the $PM_{2.5}$ NAAQS to include "quantitative milestones which are to be achieved every 3 years until the area is redesignated to attainment and which demonstrate reasonable further progress . . . toward attainment by the applicable date."

In the 2012 SIP submission, the LRAPA did not address RFP and quantitative milestone requirements. The 2012 SIP submission projected attainment of the 2006 $PM_{2.5}$ NAAQS within five years of designation, or by December 31, 2014. However, the Oakridge NAA failed to attain by December 31, 2014. The attainment plan control measures therefore did not achieve the necessary emission reductions that would have been necessary to demonstrate RFP or meet quantitative milestones, assuming such requirements were addressed in the 2012 SIP submittal. Accordingly, the EPA is proposing to disapprove the RFP and quantitative milestones elements for the 2012 SIP submission.

Contingency Measures

Section 172(c)(9) of the CAA requires that an attainment plan provide for implementation of specific contingency measures in the event that an area fails to attain a standard by its applicable attainment date, or fails to meet RFP. These measures should consist of other available control measures not included in the control strategy and must be fully adopted rules or measures that take effect without any further action by the state or the EPA. Contingency measures should also contain trigger mechanisms and an implementation schedule, and should provide for emission reductions equivalent to one year's worth of RFP (57 FR 13498).

While the LRAPA discussed contingency measures in the 2012 SIP submission, the ordinance enacting the contingency measures was not included in the SIP submission. Because the regulatory text of the contingency measures was not included in the 2012 SIP submission, the EPA is proposing to disapprove the 2012 SIP submission with respect to the contingency measure requirements of the CAA.

Motor Vehicle Emissions Budget

Section 176(c) of the CAA requires federal actions in nonattainment and maintenance areas to "conform to" the goals of SIPs. This means that such actions will not cause or contribute to violations of a NAAQS, worsen the severity of an existing violation, or delay timely attainment of any NAAQS or any interim milestone. Actions involving Federal Highway Administration (FHWA) or Federal Transit Administration (FTA) funding or approval are subject to the transportation conformity rule (40 CFR part 93, subpart A). Under this rule, metropolitan planning organizations (MPOs) in nonattainment and maintenance areas coordinate with state air quality and transportation agencies, the EPA, and the FHWA and the FTA to demonstrate that their long-range transportation plans and transportation improvement programs (TIPs) conform to applicable SIPs. This demonstration is typically determined by showing that estimated emissions from existing and planned highway and transit systems are less than or equal to the motor vehicle emissions budgets (budgets) contained in a SIP.

For budgets to be approvable, they must meet, at a minimum, the EPA's adequacy criteria (40 CFR 93.118(e)(4)). One of the adequacy criteria requires that motor vehicle emissions budgets when considered together with all other emissions sources, are consistent with the applicable requirements for reasonable further progress, attainment or maintenance (40 CFR 93.118(e)(4)(iv)). In this case the applicable requirement is attainment of the 2006 24-hour $PM_{2.5}$ NAAQS. The Oakridge NAA failed to attain the 2006 24-hour $PM_{2.5}$ NAAQS by December 31, 2014, and the submitted motor vehicle emissions budgets therefore do not meet the aforementioned adequacy criterion. Accordingly, EPA is proposing to disapprove the submitted budgets.

III. Consequences of a Disapproved SIP

This section explains the consequences of a disapproval of a SIP under the CAA. The Act provides for the imposition of sanctions and the promulgation of a federal implementation plan (FIP) if a state fails to submit and the EPA approve a plan revision that corrects the deficiencies identified by the EPA in its disapproval.

The Act's Provisions for Sanctions

If the EPA finalizes disapproval of a required SIP submission, such as an attainment plan submission, or a portion thereof, CAA section 179(a) provides for the imposition of sanctions unless the deficiency is corrected within 18 months of the final rulemaking of disapproval. The first sanction would apply 18 months after the EPA disapproves the SIP submission, or portion therefore. Under EPA's sanctions regulations, 40 CFR 52.31, the first sanction imposed would be 2:1 offsets for sources subject to the new source review requirements under section 173 of the Act. If the state has still failed to submit a SIP submission to correct the identified deficiencies for which the EPA proposes full or conditional approval 6 months after the first sanction is imposed, the second sanction will apply. The second sanction is a prohibition on the approval or funding certain highway projects.[1]

Federal Implementation Plan Provisions That Apply if a State Fails To Submit an Approvable Plan

In addition to sanctions, if the EPA finds that a state failed to submit the required SIP revision or finalizes disapproval of the required SIP revision, or a portion thereof, the EPA must promulgate a FIP no later than 2 years from the date of the finding if the deficiency has not been corrected within that time period.

Ramifications Regarding Conformity

One consequence if EPA finalizes disapproval of a control strategy SIP submission is a conformity freeze.[2] If we finalize the disapproval of the attainment demonstration SIP without a protective finding, a conformity freeze will be in place as of the effective date of the disapproval (40 CFR 93.120(a)(2)).[3] The Oakridge NAA is an isolated rural area as defined in the transportation conformity rule (40 CFR 93.101). As such it does not have a metropolitan planning organization (MPO), and there is no long range transportation plan or TIP that would be subject to a freeze. However the freeze does mean that no projects in the Oakridge NAA may be found to conform until another attainment demonstration SIP is submitted and the motor vehicle emissions budgets are found adequate or the attainment demonstration is approved.

IV. The EPA's Proposed Action

Proposed Approval

We propose to approve the following elements of the 2012 SIP submission:

- Description of the Oakridge NAA and listing as nonattainment, and
- The base year 2008 emission inventory to meet the section 172(c)(3) requirement for emissions inventories.

Proposed Disapproval

We propose to disapprove the following elements of the 2012 SIP submission:

- The attainment year emission inventory to meet the section 172(c)(3) requirement for emissions inventories,
- the section 172(c)(1) requirement for reasonably available control measures (RACM), including reasonably available control technology (RACT),
- the section 189(a)(1)(B) requirement for an attainment demonstration,
- Transportation conformity and MVEB,
- Section 172(c)(2) and section 189(c) requirements for RFP and quantitative milestones, and
- Section 172(c)(9) requirement for contingency measures.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this proposed action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would

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[1] On April 1, 1996 the US Department of Transportation published a notice in the **Federal Register** describing the criteria to be used to determine which highway projects can be funded or approved during the time that the highway sanction is imposed in an area. (*See* 61 FR 14363).

[2] Control strategy SIP revisions as defined in the transportation conformity include reasonable further progress plans and attainment demonstrations (40 CFR 93.101).

[3] EPA would give a protective finding if the submitted control strategy SIP contains adopted control measures or written commitments to adopt enforceable control measures that fully satisfy the emissions reductions requirements relevant to the statutory provision for which the implementation plan revision was submitted, such as reasonable further progress or attainment (40 CFR 93.101 and 93.120(a)(2) and (3)). The submitted attainment plan for the Oakridge NAA does not contain all necessary controls to attain the 2006 24-hour $PM_{2.5}$ NAAQS and therefore is not eligible for a protective finding.

be inconsistent with the Clean Air Act; and

- does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: July 18, 2016.

Michelle L. Pirzadeh,

Acting Regional Administrator, Region 10.

[FR Doc. 2016–17714 Filed 7–27–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 720, 721, and 723

[EPA–HQ–OPPT–2014–0650; FRL–9944–47]

RIN 2070–AJ94

Significant New Uses of Chemical Substances; Updates to the Hazard Communication Program and Regulatory Framework; Minor Amendments to Reporting Requirements for Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing changes to the existing regulations governing significant new uses of chemical substances under the Toxic Substances Control Act (TSCA) to align these regulations with revisions to the Occupational Safety and Health Administration's (OSHA) Hazard Communications Standard (HCS), which are proposed to be cross referenced, and with changes to the OSHA Respiratory Protection Standard and the National Institute for Occupational Safety and Health (NIOSH) respirator certification requirements pertaining to respiratory protection of workers from exposure to chemicals. EPA is also proposing changes to the significant new uses of chemical substances regulations based on issues that have been identified by EPA and issues raised by public commenters for Significant New Use Rules (SNURs) previously proposed and issued under these regulations. Additionally, EPA is proposing a minor change to reporting requirements for premanufacture notices (PMNs) and other TSCA section 5 notices. EPA expects these changes to have minimal impacts on the costs and burdens of complying, while updating the significant new use reporting requirements to assist in addressing any potential effects to human health and the environment.

DATES: Comments must be received on or before September 26, 2016.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2014–0650, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand deliver or delivery of boxed information, please follow the instructions at: *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Jim Alwood, Chemical Control Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–8974; email address: *alwood.jim@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture (defined by TSCA to include import), process, or use chemical substances subject to regulations in 40 CFR part 721. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Manufacturers or processors of chemical substances (NAICS codes 325 and 324), *e.g.,* chemical manufacturing, and petroleum and coals manufacturing.

B. What is the Agency's authority for taking this action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2). Such rules are called "significant new use rules" (SNURs). Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)). Section 5(a)(1)(A) of TSCA requires persons to notify EPA at least 90 days before manufacturing a new chemical substance for commercial purposes (under TSCA manufacture includes import). Section 3(9) of TSCA defines a "new chemical substance" as any substance that is not on the TSCA Inventory of Chemical Substances compiled by EPA under section 8(b) of TSCA.

C. What action is the Agency taking?

EPA is proposing changes to general requirements for SNURs in 40 CFR part 721, Significant New Uses of Chemical Substances. Most of the proposed changes are changes to the standard significant new uses for new chemical SNURs identified in subpart B which apply to chemical substances when they are cited in subpart E. Other proposed changes are procedural changes to the general provisions in subpart A that apply to all SNURs. EPA is also clarifying in the preamble of this proposed rule some definitions contained in 40 CFR part 721 and proposing a minor change to reporting requirements for TSCA section 5 notices in 40 CFR parts 720.38, 720.45 and 723.50.

D. Why is the Agency taking this action?

Based on changes that have occurred for respiratory protection requirements since 1989, as codified in NIOSH regulations at 42 CFR part 84 and the OSHA standard at 29 CFR 1910.134, EPA is proposing changes to 40 CFR 721.63. In addition, based on the changes to 29 CFR 1910.1200, OSHA's modified Hazard Communication Standard (HCS) published March 26, 2012 (77 FR 17574) (Ref. 1), EPA is proposing changes to 40 CFR 721.72. EPA is also proposing other changes to 40 CFR part 721 subparts A and B and clarifying definitions contained in 40 CFR part 721. EPA is proposing these changes and making the clarifications based on its experience in issuing and administering over 2,800 SNURs. Many of the proposed changes are based on public comments received by EPA when proposing and issuing SNURs, and questions from the public regarding current SNUR requirements such as: Considering a hierarchy of controls before using personal protective equipment to control exposures; clarifying what use other than as described in the premanufacture notice referenced in subpart E of this part for the substance means under 40 CFR 721.80(j); allowing for removal in wastewater treatment when computing estimated surface water concentrations according to 40 CFR 721.91; and revising the *bona fide* procedure in 40 CFR 721.11 to include coverage of situations where the significant new use terms are confidential.

E. What are the estimated incremental impacts of this action?

There will be a very minor increase in the overall compliance burden and cost because of the modified requirements in 40 CFR parts 720, 721, and 723. The modified SNUR requirements will be compatible with the current hazard communication requirements under 29 CFR 1910.1200 and the respiratory protection requirements at 42 CFR part 84 and 29 CFR 1910.134. The modified SNUR requirements will also allow persons subject to a SNUR that has been previously issued to use the updated requirements of 40 CFR 721.63 and 721.72 without additional rulemaking.

F. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

II. Background

On July 27, 1989 (54 FR 31298; FRL–3504–6) (Ref. 2), EPA published a final rule, titled "Significant New Use Rules; General Provisions for New Chemicals Follow-up" that put into place an expedited process for issuing SNURs for certain new chemical substances. The process applies to new chemical substances for which EPA has issued TSCA section 5(e) consent orders and other new chemical substances for which no TSCA section 5(e) consent orders have been issued, but that may present risks to human health or the environment if exposures or releases are significantly different from those described in the PMN. EPA has issued over 2,800 new chemical SNURs using these standard significant new uses. The standard designations in the sections titled "Protection in the workplace" (40 CFR 721.63) and "Hazard communication program" (40 CFR 721.72) were modeled on OSHA and NIOSH regulations that were in force at the time the rule was issued in 1989.

The July 27, 1989 final rule established subparts B, C, and D and amended subpart A of 40 CFR part 721. Subpart A contains definitions and general provisions that apply to all SNURs. In subpart B of 40 CFR part 721, EPA identified certain standard significant new uses that EPA regularly cites in new chemical SNURs. For example, EPA may consider use of a specific chemical substance to be a "significant new use" if the use does not meet requirements for protection in the workplace as described in 40 CFR 721.63(a)(1). EPA applies these standard significant new uses as appropriate when promulgating SNURs for a specific chemical substance. As explained in 40 CFR 721.50, these standard significant new use designations apply only when they are referenced as applying to a chemical substance listed in 40 CFR part 721 subpart E. Subpart C describes recordkeeping requirements for SNURs. As described in 40 CFR 721.100, these standard recordkeeping requirements apply only when they are referenced as applying to a chemical substance listed in 40 CFR part 721 subpart E. Subpart D describes an expedited process for issuing significant new use rules for new chemical substances and the process for the modification or revocation of significant new use requirements for new chemical substances. Subpart E lists significant new use and recordkeeping requirements for specific chemical substances.

On March 29, 1995 (60 FR 16311; FRL–4291–9) (Ref. 3), EPA published an amended rule titled, "Amendment for Expedited Process to Issue Significant New Use Rules for Selected New Chemical Substances." The rule amendment authorized EPA to use "significant new use" designations using expedited rulemaking procedures to promulgate SNURs for certain new chemical substances not subject to TSCA section 5(e) orders (referred to as non-section 5(e) SNURs). The amendment authorized EPA to include other designations, such as protection in the workplace and hazard communication, in non-section 5(e) SNURs promulgated via expedited rulemaking procedures.

As explained in the March 29, 1995 final rule, a TSCA section 5(e) consent order applies only to the original PMN submitter who signs the consent order, while a SNUR applies to all other manufacturers and processors of the chemical substance. The reporting requirements of a non-section 5(e) SNUR apply to all manufacturers and processors of a chemical substance including the PMN submitter. The changes to subpart B in this proposed rule would make it possible for EPA to issue non-section 5(e) SNURs as direct final rules with the updated standard SNUR designations.

How the different subparts of 40 CFR part 721 are used for new chemical SNURs and existing chemical SNURs are summarized in Table 1. New chemical SNURs are issued for certain chemical substances that have undergone PMN review. EPA typically utilizes subparts B, C, and D when issuing new chemical SNURs. Other SNURs including existing chemical SNURs may be issued for chemical substances either not on the TSCA Inventory or for those on the TSCA Inventory that typically have not undergone PMN review. EPA does not use subpart B or D for existing chemical SNURs but has applied the standard recordkeeping requirements in subpart C. The general requirements of subpart A apply to all SNURs unless they are modified in the significant new use requirements for a specific chemical substance in subpart E. Subpart E lists significant new use and recordkeeping for new and existing chemical substances.

TABLE 1—SUBPARTS USED FOR NEW CHEMICAL SNURS AND OTHER CHEMICAL SNURS

Regulation	New chemical SNURs	Other chemical SNURs
Subpart A. General Provisions (§§ 721.1–721.47)	X	X
Subpart B. Certain Significant New Uses (§§ 721.50–721.91):		
• § 721.63. Protection in the Workplace	X	
• § 721.72. Hazard Communication Program	X	
• § 721.80. Industrial, Commercial, and Consumer Activities	X	
• § 721.85. Disposal	X	
• § 721.90. Release to water	X	
• § 721.91. Concentration of estimated surface water concentrations: Instructions	X	
Subpart C. Recordkeeping Requirements (§§ 721.100–721.125)	X	X
Subpart D. Expedited Process for issuing Significant New Use Rules for Selected Chemical Substances and Limitation or Revocation of Selected Significant New Use Rules (§§ 721.160–721.185)	X	
Subpart E. Significant New Uses for Specific Chemical Substances (§§ 721.225–721.10829) *	X	X

* revised for each published SNUR.

EPA is proposing substantive changes or clarifying language in subparts A and B. The proposed changes in subpart A would affect all SNURs. The proposed changes in Subpart B may affect some previously issued new chemical SNURs already in subpart E and would affect future new chemical SNURs that would be issued using the changed terms in Subpart B. Unit III describes each proposed change and how the changes affect previously issued SNURs and SNURs that would be issued after the proposed rule becomes final. Not all of the more than 2,800 previously issued new chemical SNURs will be affected by the changes in Subpart B. For example, as described in the economic analysis for this proposed rule (Ref.13), per the EPA Chemical Data Report for Reporting Year 2011, 195 chemicals were reported in commerce and subject to new chemical SNURS. Only 60 of the 195 chemicals contained provisions for worker protection and/or hazard communication. This rule does not propose any changes to subparts C, D, or E.

In March, 2012, OSHA modified its Hazard Communication Standard (HCS) to conform to the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals (GHS) to enhance the effectiveness of the HCS by ensuring that employees are apprised of the chemical hazards to which they may be exposed, and by reducing the incidence of chemical-related occupational illnesses and injuries. (Ref. 1) The GHS is an internationally harmonized system for classifying chemical hazards and developing labels and safety data sheets. It is a set of criteria and provisions that regulatory authorities can incorporate into existing systems, or use to develop new systems.

The GHS allows a regulatory authority to choose the provisions that are appropriate to its sphere of regulation. This is referred to as the "building block approach." The GHS includes all of the regulatory components, or building blocks, that might be needed for classification and 22 labeling requirements for chemicals in the workplace, transport, pesticides, and consumer products. The modified HCS adopted those sections of the GHS that are appropriate to OSHA's regulatory sector. For example, while the GHS includes criteria on classifying chemicals for aquatic toxicity, these provisions were not adopted for the HCS because OSHA does not have the regulatory authority to address environmental concerns. The building block approach also gives regulatory agencies the authority to select which classification criteria and provisions to adopt. OSHA adopted the classification criteria and provisions for labels and SDSs, because the current HCS covers these elements. As described in Unit III, EPA is also proposing to adopt some of the GHS criteria for hazard communication pertaining to aquatic toxicity.

III. Summary of Proposed Rule

As a result of changes to OSHA and NIOSH requirements, and other issues identified through EPA's experience issuing and administering SNURs, EPA is proposing several changes to the SNUR regulations in subparts A and B. EPA will describe each proposed change and the reason for proposing the change.

1. Proposed Changes to 40 CFR 721.63, Protection in the Workplace

Based on changes that have occurred in respiratory protection requirements since 1989, per the NIOSH regulation at 42 CFR part 84 and the OSHA standard at 29 CFR 1910.134, EPA is proposing changes to 40 CFR 721.63. In June 1995, NIOSH updated and modernized its Federal regulation for testing and certifying non-powered, air-purifying, and particulate-filter respirators (42 CFR part 84). The 42 CFR part 84 respirators have passed a more demanding certification test than older respirators (*e.g.,* dust and mist [DM], dust, fume and mist [DFM], spray paint, pesticide) previously certified under 30 CFR part 11, and provide increased worker protection (Ref. 4). Because the 42 CFR part 84 test criteria simulate worst-case respirator use, NIOSH has encouraged discontinuing the use of particulate respirators certified under 30 CFR part 11 and switching to particulate respirators certified under 42 CFR part 84. However, non-powered particulate respirators that were approved under 30 CFR part 11 using the "old" labeling were allowed to be manufactured and sold until July 10, 1998. Specifically, distributors who purchased 30 CFR part 11 particulate filters and respirators prior to July 10, 1998, are able to sell them as "certified" until inventories of these products are depleted. Users who purchased such particulate filters and respirators from these distributors will be able to use them until their inventories are depleted or until the end of the shelf life or service life for these products.

Additionally, in January 1998, OSHA's revised Respiratory Protection

Standard (29 CFR 1910.134) replaced the respiratory protection standards adopted by OSHA in 1971 (Ref. 5). Subsequently, in August 2006, OSHA announced that it modified its Respiratory Protection Standard (29 CFR 1910.134) by adding definitions as well as maximum use concentration (MUC) and assigned protection factor (APF) requirements to 29 CFR 1910.134 (Ref. 6). Due to these changes, the respirators currently listed in 40 CFR 721.63 may no longer meet the current NIOSH/OSHA criteria for respirator selection and use.

EPA is proposing to update language pertaining to respiratory protection requirements that is listed in 40 CFR 721.63(a)(4), (a)(5), and (a)(6) to be consistent with both OSHA and NIOSH requirements. In 40 CFR 721.63(a)(4) which requires that respirators be used in accordance with 30 CFR part 11, EPA is proposing to replace the reference to 30 CFR part 11 with a reference to 42 CFR part 84 to cite the most updated NIOSH regulation for testing and certifying respirators. Most manufacturers and processors are already subject to and complying with 42 CFR part 84. This change would apply to all previously issued SNURs that contain significant new use requirements pertaining to respiratory protection in that it will make clear that manufacturers and processors subject to current SNURs can follow updated respiratory protection requirements without triggering a SNUN requirement; and the updated language would be cited when issuing new SNURs as appropriate. EPA is proposing updated NIOSH-certified respirator language in 40 CFR 721.63(a)(5). EPA is currently citing the new respirator language in SNURs and has not been referencing the respirators currently listed in 40 CFR 721.63(a)(5). EPA intends to continue citing the new respirator language when issuing new SNURs during the pendency of this rulemaking. The proposed updates to 40 CFR 721.63(a)(5) would standardize the use of the new respirator language by allowing EPA to cross-reference the respirator language for new chemical SNURs rather than impose the respirator language on a case-by-case basis.

EPA is proposing language that would allow persons subject to SNURs with older respirator requirements in 40 CFR 721.63(a)(5) already cited in subpart E to avoid triggering a SNUN requirement by continuing to use those respirators, if they are available. These are the 15 listed respirators in 40 CFR 721.63(a)(5)(i) through (xv). EPA is also proposing language in 40 CFR 721.63(a)(5) that would allow persons subject to the older respirator requirements in 40 CFR 721.63(a)(5)(i) through (xv) to use an equivalent respirator under the newer requirements provided that the APF of the new respirator is equal to or greater than the respirator cited in subpart E. EPA has included in the public docket a chart comparing the APF of the respirator classes in the current regulations with the corresponding older respirator requirements that can be consulted in order to determine availability of suitable substitutes (Ref. 7). The proposed language in 40 CFR 721.63(a)(6) also updates language for the airborne form of a chemical substance that would apply to the respiratory protection requirements in 40 CFR 721.63(a)(4). EPA would cite this language when issuing new SNURs.

Any personal protection equipment requirements would be a minimum set of requirements so that users are encouraged to modernize (upgrade to next generation) protective equipment to include such features as an electronic chip to identify when personnel use and discontinue use of a respirator. The electronic chip also could monitor the condition and maintenance of the respirator. EPA is specifically requesting comments on the use of next generation respirators.

EPA is also proposing a revision to 40 CFR 721.63 that would make it a significant new use not to implement a hierarchy of controls to protect workers. This revision would require persons subject to applicable SNURs to determine and use appropriate engineering and administrative controls before using personal protective equipment (PPE) for worker protection, similar to the requirements in OSHA standards at 29 CFR 1910.134(a)(1) and guidance in Appendix B to subpart I of 29 CFR 1910.

This change is being proposed partly due to comments received on recently promulgated SNURs. In response to the proposed SNURs published in the **Federal Register** of December 28, 2011 (76 FR 81447) (FRL–9326–2) (Ref. 8), EPA received comments from 26 public submissions. Each of these comments generally stated that EPA's approach of exclusively identifying the absence of adequate personal protective equipment as a significant new use instead of engineering and administrative controls is not following the best occupational health and safety practices. The commenters suggested approaches that EPA could adopt. Several commenters identified the industrial hygiene "hierarchy of controls" approach for workplace health and safety, where elimination, substitution, engineering controls, and workplace or administrative controls should be implemented before use of personal protective equipment for worker protection. Several commenters stated that persons subject to SNURs should follow the OSHA requirements to use controls that are higher in the hierarchy of controls before requiring employees to use personal protective equipment. Some commenters suggested that EPA should specifically incorporate the OSHA requirements at 29 CFR 1910.134(a)(1) into each SNUR or modify standard requirements for SNURs at 40 CFR 721.63 to require a hierarchy of controls. Other commenters noted several publications or standards that either specifically recommend a hierarchy of controls or recommend an approach using engineering controls to prevent exposures before using personal protective equipment.

In the final SNURs published on June 26, 2013 (78 FR 32810) (FRL–9390–6) (Ref. 9), EPA responded to the comments, agreeing that a hierarchy of controls should be applied and that PPE should be the last option to control exposures. EPA noted that its New Chemicals Exposure Limits language in TSCA section 5(e) consent orders already states that attempting to prevent exposures through higher controls in the hierarchy than PPE is EPA's preferred method for protecting workers. See: *http://www.epa.gov/sites/production/files/2015-06/documents/draft_ncel_insert_042115.pdf* (Ref. 10). EPA added language to the final SNURs issued June 26, 2013, that contained significant new uses pertaining to PPE for workers to require persons subject to the SNURs to consider and implement engineering controls and administrative controls where feasible. Where engineering and administrative controls are not feasible or are insufficient to protect exposed workers, persons who are subject to a SNUR must follow any PPE requirements or submit a SNUN to EPA.

All new chemical SNURs published since June 26, 2013 have included the same language to consider and implement engineering controls and administrative controls where feasible when the SNURs contained significant new uses pertaining to the lack of PPE for workers. These requirements to consider engineering and administrative controls are based on and consistent with the OSHA requirements at 29 CFR 1910.134(a)(1). EPA is proposing to revise 40 CFR 721.63(a)(1) and 40 CFR 721.63(a)(4) to add language which requires consideration and use of engineering and administrative controls where feasible before PPE for worker protection. This proposed change would affect SNURs issued after this proposed rule becomes a final effective rule and would affect previously issued SNURs that incorporate worker protection referencing the existing 40 CFR 721.63(a)(1) and 40 CFR 721.63(a)(4) regulations. EPA believes most companies are already following a hierarchy of controls due to OSHA regulations. EPA is specifically seeking comments on this proposal to incorporate a hierarchy of controls for significant new use rules.

2. Proposed Changes to 40 CFR 721.72, Hazard Communication Program

Based on the changes to 29 CFR 1910.1200, OSHA's modified HCS, EPA is proposing changes to 40 CFR 721.72. In March, 2012, OSHA modified its HCS to conform to the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals (GHS) to enhance the effectiveness of the HCS by ensuring that employees are apprised of the chemical hazards to which they may be exposed, and by reducing the incidence of chemical-related occupational illnesses and injuries. (Ref. 1) Modifications to the HCS include revised criteria for classification of chemical hazards; revised labeling provisions that include requirements for use of standardized signal words, pictograms, hazard statements, and precautionary statements; a specified format for safety data sheets; and related revisions to definitions of terms used in the HCS and requirements for employee training on labels and safety data sheets.

Under the current rules, when SNURs are issued citing section 40 CFR 721.72 in subpart E for a chemical substance, it is considered a significant new use if the company does not develop a written hazard communication program for the substance in the workplace. Paragraphs (a) through (h) of 40 CFR 721.72 can be cited in subpart E as the elements that must be included in the hazard communication program. Manufacturers and processors subject to a SNUR in subpart E for a chemical substance can rely on an existing hazard communication program, such as one established under the OSHA HCS or one based on GHS recommendations to comply with this significant new use requirement to the extent the hazard communication program contains elements cited for that SNUR from 40 CFR 721.72 paragraphs (a) through (h).

EPA is proposing to add new paragraphs (i) and (j) that EPA would use when issuing hazard communication requirements for SNURs issued after this rulemaking has been finalized. The new paragraph (i) would require that a written hazard communication program be developed and implemented for the substance in each workplace in accordance with 29 CFR 1910.1200, the OSHA HCS.

The proposed approach would maintain consistency in compliance for persons subject to TSCA and OSHA regulations for the same activity. Because the OSHA HCS is detailed and complex, by cross-referencing it EPA would avoid any errors in duplication as well as avoid the unintentional creation of additional obligations. In addition, any amendments to the OSHA HCS would apply at the same time for the purposes of complying with the SNUR. This approach would also be consistent with the requirement for EPA to coordinate with other federal executive departments and agencies under TSCA section 9(d) to impose "the least burdens of duplicative requirements on those subject to the chapter and for other purposes."

The new paragraph (j) describes specific statements and other warnings that could be required for SNURs for substances identified in subpart E. The specific statements and warnings that could be required would be based on EPA's risk assessment of the chemical substance and would be consistent with the OSHA HCS and GHS recommendations.

EPA expects that, whenever the statements in paragraphs (g), (h), and (j) are required and the determinations for the SNUR are published, manufacturers and processors subject to the SNUR will also consider if they trigger any other corresponding hazard communication requirements under the OSHA HCS or recommendations under GHS recommendations. Any hazard and precautionary statements required by the SNUR would be a minimum set of hazard warnings. EPA may also propose individual SNURs or issue section 5(e) SNURs under 40 CFR 721.160 using other specific statements, signal words, symbols, hazard category, and pictograms as hazard communication requirements.

EPA is proposing to update 40 CFR 721.72 paragraphs (a) through (h) to be consistent with both OSHA requirements and GHS recommendations. When the rulemaking is finalized, these changes would apply to individual SNURs in subpart E issued before the effective date of the final rule as described in the next two paragraphs. EPA is proposing changes to 40 CFR 721.72 paragraphs (a), (c), and (d) to change using the word material safety data sheet (MSDS) to safety data sheet (SDS) and to allow easily accessible electronic versions and other alternatives to maintaining paper copies of the SDS. These changes would apply to any previously issued SNUR in subpart E that cites these paragraphs. EPA is also proposing changes pertaining to hazard and precautionary statements that are listed in 40 CFR 721.72 paragraphs (g) and (h) to be consistent with statements required under the OSHA HCS and recommended by the GHS. The proposed changes would add new precautionary and hazard statements that are consistent with the OSHA HCS and GHS recommendations. While the previously issued SNUR precautionary and hazard statements will be retained solely for previously issued SNURs, EPA is proposing to identify which of the proposed new statements can be used as alternatives. EPA is proposing that manufacturers and processors subject to a previously issued SNUR will have the option to use the prior older precautionary and hazard statements or use the new alternative statements that are consistent with the OSHA HCS or GHS recommendations to comply with the SNUR.

EPA is also proposing language allowing any person subject to a previously issued SNUR for a substance identified in subpart E containing requirements for 40 CFR 721.72 paragraphs (a) through (h) to comply with those requirements by following the requirements of the proposed 40 CFR 721.72 paragraph (i), which is being proposed for use in future SNURs, and using any statements specified for that substance in the proposed 40 CFR 721.72 paragraphs (g) or (h). For example, a person currently subject to a SNUR citing the requirements to establish a hazard communication program as described in 40 CFR part 721.72 paragraphs (a) through (f) and the requirement for a hazard statement in paragraph (g)(1)(iii), central nervous system effects, could comply by taking the following steps: That person could establish a hazard communication program according to the requirements in the proposed paragraph (i) and use the hazard statement in paragraph (g)(1)(iii), "central nervous system effects," or the proposed alternative hazard statement (g)(1)(xi), "may cause damage to the central nervous system through prolonged or repeated exposure."

EPA recommends using a Chemical Abstracts Service (CAS) number to identify the chemical substance whenever available. EPA makes this recommendation because CAS numbers are widely used by industry including in SDSs to provide a unique identifier for chemical substances and provide an unambiguous way to identify a chemical substance, unlike the variety of possible systematic, generic, or proprietary names that may be available for the same chemical substance. Only when a CAS number is not available should a different unique numerical identifier be used. Because of variations in naming conventions for chemical substances, using CAS numbers makes it easier for the regulated community to accurately identify and report chemical identities. For example, upon importation of a chemical substance, if the chemical substance is being identified to assure compliance with regulatory requirements, providing the most specific CAS number is the most efficient and clear way to ensure this. The proposed changes for SNUR hazard communications requirements concerning how to identify chemical substances would be consistent with OSHA regulations.

3. Clarification of the Use of 40 CFR 721.80, Industrial Commercial and Consumer Activities

EPA is also clarifying its use of the significant new use for new chemical SNURs described at 40 CFR 721.80(j), which identifies as a significant new use, "Use other than as described in the premanufacture notice referenced in subpart E of this part for the substance." EPA is not proposing to change the language of 721.80(j). Instead, EPA is clarifying how it identifies as a significant new use, "Use other than as described in the premanufacture notice referenced in subpart E of this part for the substance" for individual SNURs. When EPA issues a SNUR using the designation at 40 CFR 721.80(j) in subpart E for a chemical substance and that use described in the premanufacture notice is claimed as confidential, EPA cites 40 CFR 721.80(j). See Unit III.5 for a discussion of how manufacturers and processors subject to a SNUR with a confidential significant new use designation can currently file a *bona fide* inquiry to determine whether a specific use is a significant new use and EPA's proposal for future *bona fide* inquiries. In identifying the significant new use in subpart E for certain previously issued SNURs where the use described in the premanufacture notice was not claimed confidential, EPA cited 40 CFR 721.80(j) and included the PMN use described in the premanufacture notice in parentheses. EPA has received public comments in response to proposed SNURs and pre-notice inquiries for SNUNs that manufacturers and processors subject to SNURs find it confusing when EPA cites 40 CFR 721.80(j) and then identifies the PMN use in parentheses. These comments and inquiries have stated that when EPA cites the new use this way it appears as though the significant new use is the use in the parentheses, where the significant new use is actually use other than the use in parentheses given 40 CFR 721.80(j).

To more clearly identify the significant new use, EPA has changed this procedure to only cite 40 CFR 721.80(j) when the use described in the PMN is confidential. When the use described in the PMN is not confidential, EPA intends to identify the significant new use in a new chemical SNUR by describing the use, such as in the following example: "A significant new use is any use other than as a pesticide intermediate." (This example was published in the direct final SNUR issued on February 12, 2014 (79 FR 8291) (Ref. 11) and is codified in subpart E at 40 CFR 721.10718.)

4. Proposed Changes to 40 CFR 721.91, Computation of Estimated Surface Water Concentrations: Instructions

When EPA issues a new chemical SNUR citing the significant new uses described in 40 CFR 721.90 (a)(4), (b)(4), and (c)(4), the SNUR requires significant new use notification if the results of the equation for computation of estimated surface water concentrations in 40 CFR 721.91 exceed the level specified for that SNUR in subpart E. The equation estimates surface water concentrations based on the amount of a chemical substance released from industrial processes and the flows of the water body. The current equation does not take into consideration amounts of a chemical substance released to a surface water after control technology such as wastewater treatment. EPA is proposing to revise this requirement to allow manufacturers and processors to account for reductions in surface water concentrations resulting from wastewater treatment. 40 CFR 721.91 contains instructions for the computation of estimated surface water concentrations according to the equation specified in 40 CFR 721.90 (a)(4), (b)(4), and (c)(4). EPA is proposing to revise 40 CFR 721.91 to allow for a certain percentage of removal of a chemical substance from wastewater when undergoing control technology, when using the equation to calculate surface water concentrations to meet requirements in 40 CFR 721.90. EPA has previously allowed surface water concentrations to be calculated with a consideration of wastewater treatment in certain SNURs by adding regulatory text to individual rules. This change to 40 CFR 721.91 will make the consideration of control technology part of the calculations for the equation specified in 40 CFR 721.90 when cited in subpart E for a specific chemical substance. EPA will cite the control technology and the percentage removal for SNURs in subpart E, based on EPA's assessment of the effectiveness of the control technology for the specific chemical substance. Based on past experience with new chemical SNURs, EPA expects that the control technology will usually be wastewater treatment. However, EPA will not identify a percentage of removal from wastewater for every chemical substance subject to a SNUR with the significant new use specified in 40 CFR 721.90 (a)(4), (b)(4), and (c)(4). EPA would identify an applicable removal percentage when issuing new SNURs. It does not apply to existing SNURs where a removal percentage has not been identified.

Because of numerous questions from manufacturers and processors about the phrase "predictable or purposeful release" in 40 CFR 721.90, EPA is clarifying the meaning of that phrase. The phrase is used to qualify significant new uses pertaining to releases to water in 40 CFR 721.90. As described in the proposed rule of April 29, 1987, Proposed General Provisions for New Chemicals Follow-up (52 FR 15608) (Ref. 12), the phrase predictable or purposeful does not include releases where true emergency conditions exist and significant new use notification is not possible. Therefore, routine or repeated activity that results in releases to water or non-routine releases to water that are not due to emergency conditions would be included in the term predictable or purposeful. EPA did not intend the phrase "predictable or purposeful release" to limit the agency's strict liability authority under the statute.

5. Proposed Changes to 40 CFR 721.11, Determining Whether a Chemical Substance or a Specific Use Is Subject to This Part When the Chemical Substance Identity or Significant New Use Is Confidential

Some new chemical SNURs have a significant new use designation which is a production volume limit or use other than described in the PMN that is based on CBI contained in the PMN and which is therefore not disclosed in the published SNUR. Currently, for each SNUR that contains a significant new use designation that is CBI, that SNUR cross-references the *bona fide* procedure in the specific SNUR in subpart E for 40 CFR 721.1725. That specific SNUR contains a significant new use designation that includes CBI (and is therefore not disclosed in the published SNUR) and describes the *bona fide* procedure that must be followed to allow a person to determine whether a specific use is a significant new use.

When the chemical identity in a SNUR is CBI, 40 CFR 721.11 provides a means by which *bona fide* submitters can determine whether their substance is subject to the SNUR. However, as described in the previous paragraph, chemical identity is not the only information contained in a SNUR that may be claimed as CBI. EPA is proposing to modify the *bona fide* procedure in 40 CFR 721.11 of subpart A of 40 CFR part 721 so that it applies to all SNURs that contain any confidential information in the SNUR, including the significant new use. EPA believes it would be more efficient to have a *bona fide* procedure for determining confidential significant new uses in subpart A rather than referencing 40 CFR 721.1725(b)(1) each time EPA issues a SNUR containing a confidential significant new use designation. In addition, EPA is proposing to modify the *bona fide* procedure that allows EPA to disclose the confidential significant new use designations to a manufacturer or processor who has established a *bona fide* intent to manufacture (including import) or process a particular chemical substance.

6. Proposed Changes for Submission of SDS(s) With PMNs, SNUNs, Low Volume Exemptions (LVEs), Low Release and Exposure Exemptions (LoREXs), and Test Marketing Exemption (TME) Applications

EPA is proposing to revise requirements in 40 CFR 720.38, 720.45, and 40 CFR 723.50 to require that any SDS already developed to either comply with OSHA requirements or already developed by a notice submitter for other purposes must also be submitted as part of the notification (PMN, SNUN, LVE, LoREX, or TME application) under section 5 of TSCA. Many submitters already submit available SDSs as part of their submission and the information contained in SDSs is often useful for EPA's assessments of chemicals. This proposed revision would not require submitters to develop an SDS. It would only require a submitter to submit an SDS that has already been developed to the extent it is known or reasonably ascertainable by the submitter.

7. Fixing Typographical Errors and Other Non-Substantive Changes

EPA is proposing to correct several typographical errors and more accurately use the terms manufacture, manufacturer, and manufacturing in the regulatory text of sections 40 CFR parts 720, 721, and 723.

IV. Economic Analysis

EPA evaluated the potential costs of implementing these proposed changes to section 5 SNUR requirements for potential manufacturers (including importers) and processors of the chemical substances. The proposed changes result in minimal increases in burden associated with issuing future SNURs and administration and compliance with previously issued SNURs. For new chemical SNURs, the incremental increase is estimated at 364 hours of burden with an associated $20,387 in the steady state; for section 5 notices, the incremental increase is estimated at 247 hours of burden with an associated cost of $17,843 in the steady state. The Agency's complete Economic Analysis is available in the docket under docket ID number EPA–HQ–OPPT–2014–0650 (Ref. 13).

V. References

The following is a listing of the documents that are specifically referenced in this action. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. 2012. OSHA. OSHA Revised Hazard Communication Standard; Final Rule. **Federal Register** (77 FR 17574, March 26, 2012).
2. 1989. EPA. Significant New Use Rules; General Provisions for New Chemicals Follow-up; Final Rule. **Federal Register** (54 FR 31298, July 27, 1989) (FRL–3504–6).
3. 1995. EPA. Amendment for Expedited Process to Issue Significant New Use Rules for Selected New Chemical Substances; Final Rule. **Federal Register** March 29, 1995 (60 FR 16311, March 29, 1995) (FRL–4291–9).
4. 1995. NIOSH. Respiratory Protection Devices; Final Rule. **Federal Register** (60 FR 30355, June 8, 1995).
5. 1998. OSHA. Respiratory Protection; Final Rule. **Federal Register** (63 FR 1152, January 8, 1998).
6. 2006. OSHA. Assigned Protection Factors; Final Rule. **Federal Register** (71 FR 50121, August 24, 2006).
7. 2015. EPA. Chart comparing assigned protection factors of current respirator classes with older respirator requirements.
8. 2011. EPA. Proposed Significant New Use Rules on Certain Chemical Substances; Proposed Rule. **Federal Register** (76 FR 81447, December 28, 2011) (FRL–9326–2).
9. 2013. EPA. Significant New Use Rules on Certain Chemical Substances; Final Rule. **Federal Register** (78 FR 32810, June 26, 2014) (FRL–9390–6).
10. 2015. EPA. Boilerplate consent order containing new chemicals exposure limits. *http://www.epa.gov/sites/production/files/2015-06/documents/draft_ncel_042115.pdf.*
11. 2014. EPA. Significant New Use Rules on Certain Chemical Substances; Direct Final Rule. **Federal Register** (79 FR 8291, February 12, 2014) (FRL–9903–70).
12. 1987. EPA. Significant New Uses of Chemical Substances; General Provisions for New Chemical Follow-up; Proposed Rule. **Federal Register** April 29, 1987 (52 FR 15594, April 29, 1987) (FRL–3153–6).
13. 2016. EPA. Economic Analysis for Proposed Rule Amendments to Part 721—Modifications to General and Specific Requirements in the SNUR Framework—Significant New Uses of Chemical Substances. (RIN 2070–AB27). March 2016.

VI. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

The Office of Management and Budget (OMB) has determined that this proposed rule is not a "significant regulatory action," under section 3(f) of Executive Order 12866 (58 FR 51735, October 4, 1993). Accordingly, this action was not submitted to OMB for review under Executive Order 12866 and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

An agency may not conduct or sponsor, and a person is not required to respond to an information collection request subject to the PRA (44 U.S.C. 3501 *et seq.*), unless it displays a currently valid OMB control number. The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070–0012 (EPA ICR No. 574.15). This action would not impose any burden requiring additional OMB approval. Estimates presented below reflect incremental changes associated with the rule.

Respondents/affected entities: Certain manufacturers (including importers) and processors.

Description	Number of respondents	Number of responses
Section 5 Notices	988	988
New Chemical SNURs (newly issued and previously issued)	221	334
Rule Total	1,209	1,322

Respondent's obligation to respond: Mandatory.

Frequency of Response: Incidental, upon submission of notice or implementing/updating New Chemical SNURs.

Total estimated incremental burden (hours per year): Burden is defined at 5 CFR part 178.

Description	First year	Steady state
Section 5 Notices	415	247
New Chemical SNURs (newly issued and previously issued)	661	364
Rule Total	1,073	611

Total estimated incremental cost (2014$ annual):

Description	First year	Steady state
Section 5 Notices	$30,420	$17,843
New Chemical SNURs (newly issued and previously issued)	$42,618	$20,386
Rule Total	$73,038	$38,229

In your comments on this proposed rule, EPA is also interested in any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including revisions to the automated collection techniques being used for submissions to EPA under TSCA, which are now required to use the Agency's Central Data Exchange (CDX) portal at *http://cdx.epa.gov/epa_home.asp.*

C. Regulatory Flexibility Act (RFA)

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), I hereby certify that this action would not have a significant adverse economic impact on a substantial number of small entities. The Agency's basis is briefly summarized here and is detailed in the economic analysis in the public docket for this proposed rule (Ref. 13).

Under the RFA, small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of this proposed rule on small entities, small entity is defined as: (1) A small business, as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. Since the regulated community is not expected to include small governmental jurisdictions or small not-for-profit organizations, the analysis focuses on small businesses.

EPA has observed only a very small proportion of SNUNs submitted by self-declared small businesses. To the extent that the percentage of small firms abiding by a SNUR is similar to the percentage of small firms submitting SNUNs, it is unlikely that a substantial number of small entities would be affected by this proposed rule's changes to SNUR requirements. Similarly, for section 5 notices, assuming that a similar small proportion of small firms are submitting all notices, it is likewise unlikely that substantial number of small entities would be affected by this proposed rule's changes.

EPA also believes the incremental per-response costs for complying with the proposed rule at $61 per SNUR chemical•firm and $18 per notice are low compared to the cost of developing and marketing a chemical new to the firm. Given the relatively low prevalence of small businesses in the new chemicals universe, and the extremely small incremental burden, the proposed rule is thus very unlikely to have a significant adverse economic impact on a substantial number of small entities (SISNOSE). Therefore EPA presumes a "no SISNOSE" finding. EPA continues to be interested in the potential impacts of this proposed rule on small entities and welcomes comments on issues related to such impacts.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government would be impacted by this rulemaking. As such, EPA has determined that this action would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

E. Executive Order 13132: Federalism

This action would not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in

Executive Order 13132 (64 FR 43255, August 10, 1999).

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action would not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This proposed rule would not significantly nor uniquely affect the communities of Indian Tribal governments, nor would it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175 (65 FR 67249, November 9, 2000), do not apply to this proposed rule.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a "significant energy Action" as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on energy supply, distribution, or use.

I. National Technology Transfer and Advancement Act (NTTAA)

Since this action does not involve any technical standards, NTTAA section 12(d) (15 U.S.C. 272 note) does not apply to this action.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994), because EPA has determined that this action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations.

List of Subjects in 40 CFR Parts 720, 721, and 723

Environmental protection, Chemicals, Hazardous materials, Recordkeeping, and Reporting requirements.

Dated: June 9, 2016.

Wendy Cleland-Hamnett,

Director, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 720—[AMENDED]

■ 1. The authority citation for part 720 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2613.

§ 720.1 [Amended]

■ 2. In § 720.1, remove the phrase "and importers".

■ 3. Amend § 720.3 by:

■ a. Revising paragraph (r) introductory text.

■ b. Revising paragraph (r)(1).

■ c. Revising paragraph (s) introductory text.

■ d. Revising paragraph (s)(2).

■ e. Revising paragraph (cc).

The revisions reads as follows:

§ 720.3 Definitions.

* * * * *

(r) *Manufacture for commercial purposes* means:

(1) To manufacture with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer, and includes, among other things, "manufacture" of any amount of a chemical substance or mixture:

* * * * *

(s) *Manufacture solely for export* means to manufacture for commercial purposes a chemical substance solely for export from the United States under the following restrictions on activities in the United States:

* * * * *

(2) The manufacturer and any person to whom the substance is distributed for purposes of export or processing solely for export (as defined in § 721.3 of this chapter), may not use the substance except in small quantities solely for research and development in accordance with § 720.36.

* * * * *

(cc) *Small quantities solely for research and development* (or "small quantities solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product") means quantities of a chemical substance manufactured or processed or proposed to be manufactured or processed solely for research and development that are not greater than reasonably necessary for such purposes.

* * * * *

§ 720.25 [Amended]

■ 4. In § 720.25 removing the phrase "or import" wherever it appears in the section.

§ 720.30 [Amended]

■ 5. Amend § 720.30 by:

■ a. Removing the phrase "or imported" wherever it appears in the section.

■ b. Removing in paragraph (h)(7) the word "intented" and add in its place "intended".

§ 720.36 [Amended]

■ 6. In § 720.36 removing the phrases "or imported", "or importer", "or imports" wherever they appear in the section.

■ 7. Amend § 720.38 by:

■ a. Removing the phrase "or import" wherever it appears in the section.

■ b. Adding paragraph (b)(6) to read as follows:

§ 720.38 Exemptions for test marketing.

* * * * *

(b)(6) Any safety data sheet already developed for the chemical substance.

* * * * *

§ 720.40 [Amended]

■ 8. In § 720.40, removing the phrases "or import" and "or importer" wherever they appear in the section.

■ 9. Amend § 720.45 by:

■ a. Removing in paragraph (e), the phrase "or imported" wherever it appears in the paragraph.

■ b. Adding paragraph (i) to read as follows:

§ 720.45 Information that must be included in the notice form.

* * * * *

(i) Any safety data sheet already developed for the new chemical substance.

* * * * *

§ 720.57 [Amended]

■ 10. Removing in § 720.57 paragraph (a), the word "chemcial" and add in its place "chemical".

§ 720.75 [Amended]

■ 11. In § 720.75 paragraph (e)(2), remove the phrase "or importer".

■ 12. Amend § 720.78 by:

■ a. Removing in paragraph (b)(1), the phrase "or import".

■ b. Removing in paragraph (b)(1)(iv), the word "manfacturer" and add in its place "manufacturer".

■ c. Removing in paragraph (b)(2), the phrase "or imports" wherever it appears in the paragraph.

■ d. Removing in paragraph (c) the phrase "or import".

§ 720.85 [Amended]

■ 13. Amend § 720.85 by:

■ a. Removing the phrase "or import" wherever it appears in the section.

■ b. Removing the phrase "or importing" wherever it appears in the section.

■ c. Removing in paragraph (b)(1) the phrase "or imported".

■ d. Removing in paragraph (b)(1) the word "indentity" and add in its place "identity".

■ e. Removing in paragraph (b)(2)(i) the word "manfactures" and add in its place "manufactures".

■ f. Removing in paragraph (b)(2)(i) the phrase "or imports".

■ g. Removing in paragraph (b)(3)(iv)(D) the phrase "on imported".

§ 720.90 [Amended]

■ 14. Removing throughout § 720.90 the phrase "or import" wherever it appears in the section.

■ 15. Removing throughout subpart F the phrase "or import" wherever it appears in the subpart.

§ 720.120 [Amended]

■ 16. Amend § 720.120 by:

■ a. Removing in paragraph (b) the phrase "or imports".

■ b. Removing in paragraph (b) the word "requied" and add in its place "required".

PART 721—[AMENDED]

■ 17. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

■ 18. Removing in part 721, the acronym "MSDS" and add in its place the acronym "SDS" everywhere it appears.

■ 19. Removing in part 721, the acronym "MSDSs" and add in its place the acronym "SDSs" everywhere it appears.

■ 20. Removing in part 721, the phrase "material safety" and add in its place the word "safety" everywhere it appears.

§ 721.1 [Amended]

■ 21. Removing in § 721.1(a) the phrase "manufacturers, importers and processors" and add in its place "manufacturers and processors".

■ 22. Amend § 721.3 by:

■ a. Adding in alphabetical order the definition for "Safety Data Sheet"

■ b. Revising the definition for "Customer".

■ c. Revising the definition of "Employer".

■ d. Removing the definition of "MSDS".

■ e. Revising the definition of "Non-industrial use".

■ f. Revising the definition of "Recipient".

The revisions read as follows:

Customer means any person to whom a manufacturer or processor distributes any quantity of a chemical substance, or of a mixture containing the chemical substance, whether or not a sale is involved.

Employer means any manufacturer, processor, or user of chemical substances or mixtures.

Non-industrial use means use other than at a facility where chemical substances or mixtures are manufactured or processed.

Recipient means any person who purchases or otherwise obtains a chemical substance directly from a person who manufactures or processes the substance.

Safety Data Sheet (SDS) means written or printed material concerning a hazardous chemical substance that is prepared as required under § 721.72(c).

§ 721.5 [Amended]

■ 23. Amend § 721.5 by:

■ a. Removing the phrase "manufacturer, importer, or processor" and add in its place the phrase "manufacturer or processor" everywhere it appears.

■ b. Removing the phrase "manufacture, import, or process" and add in its place the phrase "manufacture or process" everywhere it appears.

■ c. Removing in paragraph (d)(1)(iii), the word "recepient's" and add in its place "recipient's".

■ 24. Amend § 721.11 by:

■ a. Removinig the phrase "manufacturer, importer, or processor" and add in its place the phrase "manufacturer or processor" everywhere it appears.

■ b. Removing the phrase "manufacture, import, or process" and add in its place the phrase "manufacture or process" everywhere it appears.

■ c. Revising the section heading, and paragraphs (a), (e), (f), and (g).

The revisions reads as follows:

§ 721.11 Determining whether a chemical substance or a specific use is subject to this part when the chemical substance identity or significant new use is confidential.

(a) A person who intends to manufacture or process a chemical substance which is subject to a significant new use rule in subpart E of this part may ask EPA whether the substance or a proposed use is subject to the requirements of this part if that substance is described by a generic chemical name or if the significant new use is confidential and therefore not described specifically in the rule. EPA will answer such an inquiry only if EPA determines that the person has a *bona fide* intent to manufacture or process the chemical substance for commercial purposes.

* * * * *

(e) If the manufacturer or processor has shown a *bona fide* intent to manufacture or process the substance and has provided sufficient unambiguous chemical identity information to enable EPA to make a conclusive determination as to the identity of the substance, EPA will inform the manufacturer or processor whether the chemical substance is subject to this part and, if so, which section in subpart E of this part applies, and identify any confidential significant new use designations.

(f) A disclosure to a person with a *bona fide* intent to manufacture or process a particular chemical substance that the substance is subject to this part or of confidential significant new use designations will not be considered public disclosure of confidential business information under section 14 of the Act.

(g) EPA will answer an inquiry on whether a particular chemical substance is subject to this part or identify and confidential significant new uses within 30 days after receipt of a complete submission under paragraph (b) of this section.

§ 721.25 [Amended]

■ 25. Amend § 721.25 by:

■ a. Removing in paragraph (a) the phrase "manufacture, import, or processing" and add in its place the phrase "manufacture or processing".

■ b. Removing in paragraph (d) the phrase "manufacture, import, or process" and add in its place the phrase "manufacture or process".

§ 721.30 [Amended]

■ 26. Amend § 721.30 by:

■ a. Removing the phrase "manufacture, import, or processing" and add in its place the phrase "manufacture or processing" everywhere it appears.

■ b. Removing in paragraph (a) the phrase "manufacture, import, or process" and add in its place the phrase "manufacture or process".

§ 721.35 [Amended]

■ 27. Amend § 721.35 by:

■ a. Remove the phrase "manufactured, imported, or processed" and add in its place the phrase "manufactured or processed" everywhere it appears.

■ b. Removing in paragraph (f)(1) the phrase "manufacture, import, or processing" and add in its place the phrase "manufacture or processing".

■ 28. Throughout § 721.45 remove the phrase "manufactures, imports, or processes" and add in its place the phrase "manufactures or processes" everywhere it appears.

§ 721.47 [Amended]

■ 29. Revise § 721.47 by:

■ a. Removing the phrase "manufactures, imports, or processes" and add in its place the phrase "manufactures or processes" everywhere it appears.

■ b. Removing the phrase "manufacturer, importer, or processor" and add in its place the phrase "manufacturer or processor" everywhere it appears.

■ c. Removing the phrase "manufacture, import, or process" and add in its place the phrase "manufacture or process" everywhere it appears.

■ 30. Amend § 721.63 by:

■ a. Revising paragraph (a) introductory text, paragraph (a)(1), (4), and (5)

■ b. Adding new paragraphs (a)(5)(xvi) through (a)(5)(li).

■ c. Revising paragraph (a)(6).

■ d. Adding new paragraphs (a)(6)(vii) through (a)(6)(ix).

■ e. Removing in paragraph (c)(2) the phrase "manufacturer, importer, or processor" and add in its place the phrase "manufacturer or processor".

The revisions and additions read as follows:

§ 721.63 Protection in the workplace

(a) Whenever a substance is identified in subpart E of this part as being subject to this section, any manner or method of manufacturing (including importing) or processing associated with any use of the substance is considered a significant new use unless a program is established whereby:

(1) Where people are reasonably likely to have dermal or eye exposure to the chemical substance in the work area, either through direct handling of the substance, or through contact with surfaces on which the substance may exist, or because the substance becomes airborne in the form listed in paragraph (a)(6) of this section, and the form is cited in subpart E of this part for the chemical substance, engineering control measures (*e.g.*, enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.*, workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. Where engineering, work practice, and administrative controls are not feasible or dermal or eye exposure is still reasonably likely, each person who is reasonably likely to be exposed to the chemical substance by dermal or eye exposure must be provided with, and is required to wear, personal protective equipment (PPE) to prevent dermal or eye exposure to the substance. Refer to 29 CFR 1910.132 and 29 CFR 1910.133 for requirements on selection and use of PPE.

* * * * *

(4) Where each person who is reasonably likely to be exposed to the chemical substance by inhalation in the work area in one or more of the forms listed in paragraph (a)(6) of this section and cited in subpart E of this part for the chemical substance, engineering control measures (*e.g.*, enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.*, workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. When engineering, work practice, and administrative controls are not feasible or inhalation exposure is still reasonably likely, each person who is reasonably likely to be exposed to the chemical substance by inhalation in the work area in one or more of the forms listed in paragraph (a)(6) of this section and cited in subpart E of this part for the chemical substance, must be provided with, and is required to wear, a NIOSH-certified respirator from one of the categories listed in paragraph (a)(5) of this section. Refer to 29 CFR 1910.134 and 42 CFR part 84 for requirements on the selection, use, and maintenance of respirators, including establishing respiratory protection program, medical determination, and other administrative and programmatic requirements for respiratory protection.

(5) The following NIOSH-certified respirators meet the requirements for paragraph (a)(4) of this section:

* * * * *

(xvi) NIOSH-certified N100 (if oil aerosols absent), R100, or P100 filtering facepiece respirator. (APF = 10)

(xvii) NIOSH-certified air-purifying half-mask respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters. (APF = 10)

(xviii) NIOSH-certified air-purifying half mask respirator equipped with appropriate gas/vapor cartridges. (APF = 10)

(xix) NIOSH-certified air-purifying half-mask respirator equipped with appropriate gas/vapor cartridges in combination with N100, R100, or P100 filters or an appropriate canister incorporating N100, R100, or P100 filters. (APF = 10)

(xx) NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a half-mask. (APF = 10)

(xxi) NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a half mask. (APF = 10)

(xxii) NIOSH-certified powered air-purifying respirator equipped with a hood or helmet and HEPA filters. (APF = 25)

(xxiii) NIOSH-certified powered air-purifying respirator with a hood or helmet equipped with appropriate gas/vapor cartridges. (APF = 25)

(xxiv) NIOSH-certified powered air-purifying respirator with a hood or helmet and with appropriate gas/vapor cartridges in combination with HEPA filters. (APF = 25)

(xxv) NIOSH-certified powered air-purifying respirator equipped with a loose fitting facepiece and HEPA filters. (APF = 25)

(xxvi) NIOSH-certified powered air-purifying respirator equipped with a loose fitting facepiece with appropriate gas/vapor cartridges. (APF = 25)

(xxvii) NIOSH-certified powered air-purifying respirator equipped with a loose fitting facepiece with appropriate gas/vapor cartridges in combination with HEPA filters. (APF = 25)

(xxviii) NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet. (APF = 25)

(xxix) NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece. (APF = 25)

(xxx) NIOSH-certified air-purifying full facepiece respirator equipped with N100, R–100, or P–100 filter(s). (APF = 50)

(xxxi) NIOSH-certified air-purifying full facepiece respirator equipped with appropriate gas/vapor cartridges or canisters. (APF = 50)

(xxxii) NIOSH-certified air-purifying full facepiece respirator equipped with appropriate gas/vapor cartridges in combination with N100, R100, or P100 filters or an appropriate canister incorporating N100, R100, or P100 filters. (APF = 50)

(xxxiii) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting half mask and HEPA filters. (APF = 50)

(xxxiv) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting half mask and appropriate gas/vapor cartridges or canisters. (APF = 50)

(xxxv) NIOSH-certified powered air-purifying respirator with a tight-fitting half mask and appropriate gas/vapor cartridges in combination with HEPA filters. (APF = 50)

(xxxvi) NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a half-mask. (APF = 50)

(xxxvii) NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a full facepiece. (APF = 50)

(xxxviii) NIOSH-certified continuous flow supplied-air respirator equipped with a tight-fitting half mask. (APF = 50)

(xxxix) NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece. (APF = 50)

(xl) NIOSH-certified powered air purifying full facepiece respirator equipped with HEPA filters. (APF = 1,000)

(xli) NIOSH-certified powered air purifying full facepiece respirator equipped with appropriate gas/vapor cartridges. (APF = 1,000)

(xlii) NIOSH-certified powered air purifying fill facepiece respirator equipped with appropriate gas/vapor cartridges in combination with HEPA filters. (APF = 1,000)

(xliii) NIOSH-certified powered air-purifying respirator equipped with a hood or helmet and N100, R100, or P100 filters *with evidence demonstrating protection level of 1,000 or greater.* See 40 CFR 721.63(a)(5)(li). (APF = 1,000)

(xliv) NIOSH-certified powered air-purifying respirator equipped with a hood or helmet and appropriate gas/vapor cartridges *with evidence demonstrating protection level of 1,000 or greater.* See 40 CFR 721.63(a)(5)(li). (APF = 1,000)

(xlv) NIOSH-certified powered air-purifying respirator with a loose-fitting hood or helmet that is equipped with an appropriate gas/vapor cartridge in combination with HEPA filters *with evidence demonstrating protection level of 1,000 or greater.* See 40 CFR 721.63(a)(5)(li). (APF = 1,000)

(xlvi) NIOSH-certified continuous flow supplied-air respirator equipped with a full facepiece. (APF = 1,000)

(xlvii) NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet *with evidence demonstrating protection level of 1,000 or greater.* See 40 CFR 721.63(a)(5)(li). (APF = 1,000)

(xlviii) NIOSH-certified pressure-demand supplied-air respirator equipped with a full facepiece. (APF = 1,000)

(xlix) NIOSH-certified pressure-demand or other positive-pressure mode (*e.g.,* open/closed circuit) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece. (APF = 10,000)

(l) If one of the respirators in paragraph (a)(5)(i) through (a)(5)(xv) is cited for a substance identified in subpart E an employer may substitute a respirator from paragraphs (a)(5)(xvi) through (a)(5)(xlix) as long as its assigned protection factor is equal to or greater than the respirator cited in subpart E for that substance.

(li) Without testing data that demonstrates a level of protection of 1,000 or greater, all air purifying respirators and supplied air respirators with helmets/hoods are to be treated as loose-fitting facepiece respirators with an APF of 25.

(6) When cited in subpart E of this part for a substance, the following airborne form(s) of the substance, in combination or alone, are referenced by paragraphs (a)(1) and (4) of this section:

* * * * *

(vii) Particulate or aerosol (solids or liquid droplets suspended in a gas; *e.g.,* dust, fume, mist, smoke).

(viii) Gas/vapor.

(ix) Combination particulate and gas/vapor (gas and liquid/solid physical forms are both present, *e.g.,* particulates and acid gases or particulates and organic vapors).

* * * * *

(c) * * *

(2) If, after receiving a statement of assurance from a recipient under paragraph (c)(1)(ii) of this section, a manufacturer or processor has knowledge that the recipient is engaging in an activity that is not consistent with the implementation of the program specified in paragraph (a) of this section, that person is considered to have knowledge that the person is engaging in a significant new use and is required to follow the procedures in § 721.5(d).

* * * * *

■ 31. Amend § 721.72 by:
■ a. Revising the introductory text paragraph.
■ b. Revising paragraph (a) and (1).
■ c. Revising paragraph (b)(5).
■ d. Revising paragraph (c)(5), (7) and (9).
■ e. Revising paragraph (g)(1) introductory text and paragraphs (g)(1)(i) through (g)(1)(ix).
■ f. Adding paragraphs (g)(1)(x) through (g)(1)(xiv).
■ g. Revising paragraph (g)(2) introductory text and paragraphs (g)(2)(i) through (g)(2)(v).
■ h. Adding paragraphs (g)(2)(vi) through (g)(2)(viii).
■ i. Revising paragraphs (g)(3)(i) through (g)(3)(ii).
■ j. Adding paragraph (g)(3)(iii).
■ k. Revising paragraphs (g)(4)(i) through (g)(4)(iii).
■ l. Adding paragraph (g)(4)(iv).
■ m. Revising paragraph (h)(1)(ii) introductory text and paragraphs (h)(1)(ii)(A) through (h)(1)(ii)(I).
■ n. Adding paragraphs (h)(1)(ii)(J) through (h)(1)(ii)(N).
■ o. Revising paragraphs (h)(1)(iii)(A) through (h)(1)(iii)(E).
■ p. Adding paragraphs (h)(1)(iii)(F) through (h)(1)(iii)(H).
■ q. Revising paragraph (h)(1)(iv) introductory text and paragraphs (h)(1)(iv)(A) through (h)(1)(iv)(B).
■ r. Adding paragraph (h)(1)(iv)(C).
■ s. Revising paragraphs (h)(1)(v)(A) through (h)(1)(v)(C).
■ t. Adding paragraph (h)(1)(v)(D).
■ u. Revising paragraph (h)(2)(ii) introductory text and paragraphs (h)(2)(ii)(A) through (h)(2)(ii)(I).
■ v. Adding paragraphs (h)(2)(ii)(J) through (h)(2)(ii)(N).
■ w. Revising paragraph (h)(2)(iii) introductory text and paragraphs (h)(2)(iii)(A) through (h)(2)(iii)(E).
■ x. Adding paragraphs (h)(2)(iii)(F) through (h)(2)(iii)(H)
■ y. Revising paragraph (h)(2)(iv) introductory text and paragraphs (h)(2)(iv)(A) and (h)(2)(iv)(B).
■ z. Adding paragraph (h)(2)(iv)(C).
■ aa. Revising paragraphs (h)(2)(v)(A) through (h)(2)(v)(C).
■ bb. Adding paragraph (h)(2)(v)(D).
■ cc. Adding paragraphs (i) and (j).

The revisions and additions read as follows:

§ 721.72 Hazard communication program.

Whenever a substance is identified in subpart E of this part as being subject to this section, a significant new use of that substance is any manner or method of manufacture (including import) or processing associated with any use of that substance without establishing a hazard communication program as described in this section. Paragraphs (a) through (h) apply to SNURs issued before September 26, 2016. Paragraphs (i) and (j) apply to SNURs issued on or after September 26, 2016. Any person subject to the requirements of paragraphs (a) through (h) have the option of following the requirements of paragraph (i) or using the statements specified in paragraphs (g) or (h).

(a) *Written hazard communication program.* Each employer shall develop and implement a written hazard communication program for the substance in each workplace. The written program will, at a minimum, describe how the requirements of this section for labels, SDSs, and other forms of warning material will be satisfied. The employer must make the written hazard communication program available, upon request, to all employees, contractor employees, and their designated representatives. The employer may rely on an existing hazard communication program, including an existing program established under the Occupational Health and Safety Administration (OSHA) Hazard Communication Standard in 29 CFR 1910.1200 of 2012 to comply with this paragraph provided that the existing hazard communication program satisfies the requirements of this paragraph. The written program shall include the following:

(1) A list of each substance identified in subpart E of this part as subject to this section known to be present in the work area. The list must be maintained in the work area and must use the identity provided on the appropriate SDS for each substance required under paragraph (c) of this section. The list may be compiled for the workplace or for individual work areas.

* * * * *

(b) * * *

(5) If the label or alternative form of warning is to be applied to a mixture containing a substance identified in subpart E of this part as subject to this section in combination with another substance identified in subpart E of this part and/or a substance defined as a "hazardous chemical" under the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29 CFR 1910.1200), the employer may prescribe on the label, SDS, or alternative form of warning, the measures to control worker exposure or environmental release which the employer determines provide the greatest degree of protection. However, should these control measures differ from the applicable measures required under subpart E of this part, the employer must seek a determination of equivalency for such alternative control measures pursuant to § 721.30 before prescribing them under this paragraph (b)(5).

* * * * *

(c) * * *

(5) If the employer becomes aware of any significant new information regarding the hazards of the substance or ways to protect against the hazards, this new information must be added to the SDS within 3 months from the time the employer becomes aware of the new information. If the substance is not currently being manufactured, processed, or used in the employer's workplace, the employer must add the new information to the SDS before the substance is reintroduced into the workplace.

* * * * *

(7) The employer must maintain a copy of the SDS in its workplace, and must ensure that it is readily accessible during each work shift to employees when they are in their work areas. (Easy and immediate electronic access and other alternatives to maintaining paper copies of the safety data sheets are permitted as long as complete and accurate versions of the SDS are available immediately to employees in each workplace by such options.)

* * * * *

(9) The SDS must be in English; however, the information may be repeated in other languages.

* * * * *

(g) * * *

(1) Human health hazard statements:

(i) Causes skin irritation.

(ii) Respiratory complications. (You may also use paragraph (g)(1)(x) of this section for this designation.).

(iii) Central nervous system effects. (You may also use paragraph (g)(1)(xi) of this section for this designation but you must include this specific effect.)

(iv) Internal organ effects. (You may also use paragraph (g)(1)(xi) of this section for this designation.)

(v) Birth defects. (You may also use paragraph (g)(1)(xii) of this section for this designation but you must include this specific effect.)

(vi) Reproductive effects. (You may also use paragraph (g)(1)(xii) of this section for this designation but you must include this specific effect.)

(vii) May cause cancer.

(viii) Immune system effects. (You may also use paragraph (g)(1)(xi) of this section for this designation but you must include this specific effect.)

(ix) Developmental effects. (You may also use paragraph (g)(1)(xii) of this section for this designation but you must include this specific effect.)

(x) May cause allergy or asthma symptoms or breathing difficulties if inhaled.

(xi) May cause damage to organs <. . .> through prolonged or repeated exposure.

<. . .> (State all organs identified in subpart E of this part for this substance.).

(xii) May damage fertility or the unborn child <. . .>.

<. . .> (State specific effect identified in subpart E of this part for this substance.)

(xiii) May cause an allergic skin reaction.

(xiv) Causes eye irritation.

(2) Human health hazard precautionary statements:

(i) Avoid skin contact. (You may also use paragraph (g)(2)(vi) of this section for this designation.)

(ii) Avoid breathing substance. (You may also use paragraph (g)(2)(viii) of this section for this designation.)

(iii) Avoid ingestion.

(iv) Use respiratory protection. (You may also use paragraph (g)(2)(vii) of this section for this designation.)

(v) Use skin protection. (You may also use paragraph (g)(2)(vi) of this section for this designation.)

(vi) Wear protective gloves/protective clothing/eye protection/face protection. Chemical manufacturer or distributor to specify type of equipment, as required.)

(vii) Wear respiratory protection. (Chemical manufacturer or distributor to specify equipment as required.)

(viii) Avoid breathing dust/fume/gas/mist/vapors/spray. (Chemical manufacturer or distributor to specify applicable conditions.)

(3) * * *

(i) Toxic to fish. (You may also use paragraph (g)(3)(iii) of this section for this designation.)

(ii) Toxic to aquatic organisms. (You may also use paragraph (g)(3)(iii) of this section for this designation.)

(iii) Toxic to aquatic life.

(4) * * *

(i) Disposal restrictions apply. (You may also use paragraph (g)(4)(iv) of this section for this designation.)

(ii) Spill clean-up restrictions apply. (You may also use paragraph (g)(4)(iv) of this section for this designation.)

(iii) Do not release to water. (You may also use paragraph (g)(4)(iv) of this section for this designation.)

(iv) Dispose of contents/container to . . . (Specify disposal requirements in subpart E of this part and whether they apply to contents, container or both.)

* * * * *

(h)(1) * * *

(ii) *Human health hazard statements.*

(A) Causes skin irritation.

(B) Respiratory complications. (You may also use paragraph (h)(1)(ii)(J) of this section for this designation.)

(C) Central nervous system effects. (You may also use paragraph (h)(1)(ii)(K) of this section for this designation but you must include this specific effect.)

(D) Internal organ effects. (You may also use paragraph (h)(1)(ii)(K) of this section for this designation.)

(E) Birth defects. (You may also use paragraph (h)(1)(ii)(L) of this section for this designation but you must include this specific effect.)

(F) Reproductive effects. (You may also use paragraph (h)(1)(ii)(L) of this section for this designation but you must include this specific effect.)

(G) Cancer.

(H) Immune system effects. (You may also use paragraph (h)(1)(ii)(K) of this section for this designation but you must include this specific effect.)

(I) Developmental effects. (You may also use paragraph (h)(1)(ii)(L) of this section for this designation but you must include this specific effect.)

(J) May cause allergy or asthma symptoms or breathing difficulties if inhaled.

(K) May cause damage to organs <. . .> through prolonged or repeated exposure.

<. . .> (state all organs identified in subpart E of this part for this substance.)

(L) May damage fertility or the unborn child <. . .>.

<. . .> (state specific effect identified in subpart E of this part for this substance.)

(M) May cause an allergic skin reaction.

(N) Causes eye irritation.

(iii) *Human health hazard precautionary statements.*

(A) Avoid skin contact. (You may also use paragraph (h)(1)(iii)(F) of this section for this designation.)

(B) Avoid breathing substance. (You may also use paragraph (h)(1)(iii)(H) of this section for this designation.)

(C) Avoid ingestion.

(D) Use respiratory protection. (You may also use paragraph (h)(1)(iii)(G) of this section for this designation.)

(E) Use skin protection. (You may also use paragraph (h)(1)(iii)(F) of this section for this designation.)

(F) Wear protective gloves/protective clothing/eye protection/face protection. (Chemical manufacturer or distributor to specify type of equipment, as required.)

(G) Wear respiratory protection. (Chemical manufacturer or distributor to specify equipment as required.)

(H) Avoid breathing dust/fume/gas/mist/vapors/spray. (Chemical manufacturer or distributor to specify applicable conditions.)

(iv) *Environmental hazard statements.*

(A) Toxic to fish. (You may also use paragraph (h)(1)(iv)(C) of this section for this designation.)

(B) Toxic to aquatic organisms. (You may also use paragraph (h)(1)(iv)(C) of this section for this designation.)

(C) Toxic to aquatic life.

(v) *Environmental hazard precautionary statements.* Notice to Users:

(A) Disposal restrictions apply. (You may also use paragraph (h)(1)(v)(D) of this section for this designation)

(B) Spill clean-up restrictions apply. (You may also use paragraph (h)(1)(v)(D) of this section for this designation)

(C) Do not release to water. (You may also use paragraph (h)(1)(v)(D) of this section for this designation.)

(D) Dispose of contents/container to . . . (Specify disposal requirements in subpart E of this part and whether they apply to contents, container or both.)

* * * * *

(2) * * *

(ii) *Human health hazard statements.*

(A) Causes skin irritation.

(B) Respiratory complications. (You may also use paragraph (h)(2)(ii)(J) of this section for this designation.)

(C) Central nervous system effects. (You may also use paragraph (h)(2)(ii)(K) of this section for this designation but you must include this specific effect.)

(D) Internal organ effects. (You may also use paragraph (h)(2)(ii)(K) of this section for this designation.)

(E) Birth defects. (You may also use paragraph (h)(2)(ii)(L) of this section for this designation but you must include this specific effect.)

(F) Reproductive effects. (You may also use paragraph (h)(2)(ii)(L) of this section for this designation but you must include this specific effect.)

(G) May cause cancer.

(H) Immune system effects. (You may also use paragraph (h)(2)(ii)(K) of this section for this designation but you must include this specific effect.)

(I) Developmental effects. (You may also use paragraph (h)(2)(ii)(L) of this section for this designation but you must include this specific effect.)

(J) May cause allergy or asthma symptoms or breathing difficulties if inhaled.

(K) May cause damage to organs <. . .> through prolonged or repeated exposure.<. . .> (state all organs identified in subpart E for this substance.)

(L) May damage fertility or the unborn child <. . .>.<. . .> (state specific effect identified in subpart E for this substance.)

(M) May cause an allergic skin reaction.

(N) Causes eye irritation.

(iii) *Human health hazard precautionary statements.*

(A) Avoid skin contact. (You may also use paragraph (h)(2)(iii)(F) of this section for this designation.)

(B) Avoid breathing substance. (You may also use paragraph (h)(2)(iii)(H) of this section for this designation.)

(C) Avoid ingestion.

(D) Use respiratory protection. (You may also use paragraph (h)(2)(iii)(G) of this section for this designation.)

(E) Use skin protection. (You may also use paragraph (h)(2)(iii)(F) of this section for this designation.)

(F) Wear protective gloves/protective clothing/eye protection/face protection.

(Chemical manufacturer or distributor to specify type of equipment, as required.)

(G) Wear respiratory protection. (Chemical manufacturer or distributor to specify equipment as required.)

(H) Avoid breathing dust/fume/gas/mist/vapors/spray. (Chemical manufacturer or distributor to specify applicable conditions.)

(iv) *Environmental hazard statements.*

(A) Toxic to fish. (You may also use paragraph (h)(2)(iv)(C) of this section for this designation.)

(B) Toxic to aquatic organisms. (You may also use paragraph (h)(2)(iv)(C) of this section for this designation.)

(C) Toxic to aquatic life.

(v) *Environmental hazard precautionary statements.* Notice to Users:

(A) Disposal restrictions apply. (You may also use paragraph (h)(2)(v)(D) of this section for this designation.)

(B) Spill clean-up restrictions apply. (You may also use paragraph (h)(2)(v)(D) of this section for this designation.)

(C) Do not release to water. (You may also use paragraph (h)(2)(v)(D) of this section for this designation.)

(D) Dispose of contents/container to . . . (Specify disposal requirements in subpart E of this part and whether they apply to contents, container or both.)

(i) *Written hazard communication program.* Each employer shall develop and implement a written hazard communication program for the substance in each workplace in accordance with 29 CFR 1910.1200.

(j) *Human health, environmental hazard, exposure, and precautionary statements.* In addition to the requirements for the hazard communication program specified in paragraph (i), whenever referenced in subpart E of this part for a substance, the following human health and environmental hazard, exposure, and precautionary statements shall appear as specified in paragraph (i) of this section.

(1) Human health hazard statements:

(i) Causes skin irritation.

(ii) May cause cancer.

(iii) Immune system effects.

(iv) Developmental effects.

(v) May cause allergy or asthma symptoms or breathing difficulties if inhaled.

(vi) May cause damage to organs <. . .>through prolonged or repeated exposure.<. . .> (state all organs identified in subpart E for this substance.)

(vii) May damage fertility or the unborn child<. . .>.<. . . >(state specific effect identified in subpart E for this substance.)

(viii) May cause an allergic skin reaction.

(ix) Causes eye irritation.

(2) Human health hazard precautionary statements:

(i) Avoid ingestion.

(ii) Wear protective gloves/protective clothing/eye protection/face protection. (Chemical manufacturer or distributor to specify type of equipment, as required.)

(iii) Wear respiratory protection. (Chemical manufacturer or distributor to specify equipment as required.)

(iv) Avoid breathing dust/fume/gas/mist/vapors/spray. (Chemical manufacturer or distributor to specify applicable conditions.)

(3) Environmental hazard statements: This substance may be:

(i) Toxic to aquatic life.

(ii) Very toxic to aquatic life.

(iii) Harmful to aquatic life.

(iv) Very toxic to aquatic life with long term effects.

(v) Toxic to aquatic life with long lasting effects.

(vi) Harmful to aquatic life with long lasting effects.

(vii) May cause long lasting harmful effects to aquatic life.

(4) Environmental hazard precautionary statements: Notice to users:

(i) Avoid release to the environment (if this is not the intended use.)

(ii) Collect spillage.

(iii) Dispose of contents/container to . . . (Specify disposal requirements in subpart E of this part and whether they apply to contents, container or both.)

§ 721.80 [Amended]

■ 32. Amend § 721.80 by:

■ a. Removing the phrase "or import" wherever it appears in the section.

■ b. Removing the phrase "and importation" wherever it appears in the section.

■ c. Removing the phrase "or importer" wherever it appears in the section.

■ d. Removing the word "manufacture" wherever it appears and add in its place the word "manufacturing".

§ 721.85 [Amended]

■ 33. In § 721.85, remove the word "supercede" wherever it appears and add in its place the word "supersede".

■ 34. Amend § 721.91 by:

■ a. Revising the introductory paragraph, and

■ b. Adding paragraph (a)(7).

The revision reads as follows:

§ 721.91 Computation of estimated surface water concentrations: Instructions.

These instructions describe the use of the equation specified in § 721.90(a)(4), (b)(4), and (c)(4) to compute estimated surface water concentrations which will result from release of a substance identified in subpart E of this part. The equation shall be computed for each site using the stream flow rate appropriate for the site according to paragraph (b) of this section, and the highest number of kilograms calculated to be released for that site on a given day according to paragraph (a) of this section. Two variables shall be considered in computing the equation, the number of kilograms released, and receiving stream flow.

(a) * * *

(7) When a substance is designated in subpart E of this part with a specific control technology and a percentage removal of the substance from wastewater resulting from use of the specified control technology, you may subtract that percentage from the highest expected daily release if that control technology is applied.

* * * * *

§ 721.100 [Amended]

■ 35. In § 721.100, remove the phrase "manufacturers, importers, and processors" and add in its place "manufacturers and processors".

■ 36. Amend § 721.125 by revising the introductory paragraph, paragraph (a), (c), and (j) to read as follows:

§ 721.125 Recordkeeping requirements.

At the time EPA adds a substance to subpart E of this part, EPA will specify appropriate recordkeeping requirements which correspond to the significant new use designations for the substance selected from subpart B of this part. Each manufacturer and processor of the substance shall maintain the records for 5 years from the date of their creation. In addition to the records specified in § 721.40, the records whose maintenance this section requires may include the following:

(a) Records documenting the manufacturing volume of the substance and the corresponding dates of manufacture.

* * * * *

(c) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture or processing to whom the manufacturer or processor directly sells or transfers the substance, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date.

* * * * *

(j) Records documenting compliance with any applicable disposal requirements under § 721.85, including the method of disposal, location of disposal sites, dates of disposal, and volume of the substance disposed. Where the estimated disposal volume is not known to or reasonably ascertainable by the manufacturer or processor, that person must maintain other records which demonstrate establishment and implementation of a program that ensures compliance with any applicable disposal requirements.

* * * * *

§ 721.160 [Amended]

■ 37. Amend § 721.160 by:

■ a. Removing in paragraph (a)(1) the phrase "and import".

■ b. Removing in paragraph (a)(2) the phrase "or import".

PART 723—[AMENDED]

■ 38. The authority citation for part 723 continues to read as follows:

Authority: 15 U.S.C. 2604.

■ 39. Amend § 723.50 by:

■ a. Revising paragraph (a)(1) introductory text.

■ b. Revising paragraph (e)(2)(xi)(A).

■ c. Adding paragraph (e)(2)(xiii).

The revisions read as follows:

§ 723.50 Chemical substances manufactured in quantities of 10,000 kilograms or less per year, and chemical substances with low environmental releases and human exposures

(a) * * *

(1) This section grants an exemption from the premanufacture notice requirements of section 5(a)(1)(A) of the Toxic Substances Control Act (15 U.S.C. 2604(a)(1)(A)) for the manufacture of:

* * *

(e) * * *

(2) * * *

(xi) * * *

(A) The manufacturer intends to manufacture the new chemical substance for commercial purposes, other than in small quantities solely for research and development, under the terms of this section.

* * *

(xiii) Safety Data Sheet (§ 720.45(i)).

* * * * *

§ 723.175 [Amended]

■ 40. Amend § 723.175 by:

■ a. Removing in paragraph (f)(2)(iii), the word "imprevious" and add in its place "impervious".

■ b. Removing in paragraph (g), the word "chemcial" and add in its place "chemical".

■ c. Removing in paragraph (h)(2), the phrase "chemcial subtance" and add in its place "chemical substance".

■ d. Removing in paragraph (i)(1)(ii)(A), the word "disagram" and add in its place "diagram".

■ e. Removing in paragraph (i)(1)(ii)(C), the word "indentify" and add in its place "identify".

■ f. Removing in paragraph (i)(1)(iii), the word "chemcial" and add in its place "chemical".

§ 723.250 [Amended]

■ 41. Amend § 723.250 by:

■ a. Removing in paragraph (e)(3) the phrase "composition, complex" and add in its place "composition, complex".

■ b. Removing in paragraph (j)(1), the phrase "or import".

[FR Doc. 2016–15005 Filed 7–27–16; 8:45 am]

BILLING CODE 6560–50–P

SURFACE TRANSPORTATION BOARD

49 CFR Part 1244

[Docket No. EP 385 (Sub-No. 7)]

Waybill Data Reporting for Toxic Inhalation Hazards; Withdrawal

AGENCY: Surface Transportation Board.

ACTION: Proposed rule, withdrawal.

SUMMARY: The Surface Transportation Board is withdrawing the proposed rules and discontinuing the EP 385 (Sub-No. 7) rulemaking proceeding which proposed to expand the Waybill Sample collection with respect to traffic movements designated as a Toxic Inhalation Hazard.

DATES: The proposed rule published on February 2, 2010 (75 FR 5261) is withdrawn and the rulemaking proceeding is discontinued on July 28, 2016.

FOR FURTHER INFORMATION CONTACT: Allison Davis at (202) 245–0378. Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: On January 28, 2010, in the above titled docket, the Board issued a Notice of Proposed Rulemaking (NPR) seeking public comment on a proposal to expand information that certain railroads are required to submit to the Board for purposes of the carload Waybill Sample (75 FR 5261, February 2, 2010). Specifically, the proposal would require railroads to submit information about all traffic movements designated as a Toxic Inhalation Hazard (TIH).

As explained below, this proceeding will be discontinued.

The Waybill Sample is the Board's primary source of information about freight rail shipments terminating in the United States. A waybill is a document describing the characteristics of an individual rail shipment, and includes (among other things) the following information: The originating and terminating freight stations, the railroads participating in the movement, the points of all railroad interchanges, the number of cars, the car initial and number, the movement weight in hundredweight, the commodity, and the freight revenue. Currently, railroads that are required to file Waybill Sample information may report a random sample of as little as 1% (using the manual system) or 2.5% (using the computerized system) of carloads on a waybill. *See* 49 CFR 1244.4(b) and (c).[1]

In the NPR, the Board suggested that the expanded information gathered from the proposed rule would permit the Board to assess TIH traffic within the United States more accurately. The NPR also stated that the information would be beneficial in Three-Benchmark rail rate cases involving TIH traffic, giving parties a larger number of movements from which to develop comparison groups. The additional information would also assist the Board in quantifying the magnitude of TIH traffic, and would help the Board more accurately measure the associated costs of handling such traffic.

On March 4, 2010, the Association of American Railroads (AAR) filed the single comment received in response to the NPR. The AAR agrees that expanded TIH waybill data for use in Three-Benchmark rate cases would be useful; but, it expressed several security-related concerns regarding the potential use of TIH-related data the Board proposed to collect. (AAR Comments 2, 7.)[2] The AAR submits that, in light of the sensitive nature of detailed TIH waybill data, the Board should not collect and maintain this data and subject it to potential inadvertent disclosure unnecessarily. (*Id.* at 8.) The AAR suggests several alternatives to the Board's proposal. First, the AAR suggests disclosure on a case-by-case basis, where the defendant carrier in a Three-Benchmark rate proceeding would make all TIH waybills available to the complainant for the most current period. (*Id.* at 8.) Second, the AAR suggests that the Board could assess TIH traffic by obtaining data from the Transportation Security Administration, which collects some of the data that would be found in the Waybill Sample. (*Id.*) Lastly, the AAR suggests that, if the Board were to collect 100% of TIH waybill data, then the Board should restrict access to the data and house the data in a secure separate file. (*Id.* at 10–14.)

The Board appreciates and understands the AAR's concerns about security as it relates to TIH traffic. Without commenting on the AAR's suggested alternatives, we will discontinue this proceeding. Taking into consideration the security concerns raised and the lack of broader comment on the NPR, we will not move forward with the proposed rule and will discontinue this docket in the interest of administrative finality. However, the Board will consider ways to address this issue as part of future proceedings.

Decided: July 21, 2016.

By the Board, Chairman Elliott, Vice Chairman Miller, and Commissioner Begeman. Commissioner Begeman commented with a separate expression.

COMMISSIONER BEGEMAN, commenting:

This proceeding was initiated in January 2010, well before a majority of the current members began serving here. The only real action that has occurred on this matter that I am aware of was when the Association of American Railroads filed its comments in March 2010. Since that time, the Board could have worked to meaningfully address AAR's concerns and ultimately improve the proposal. Yet no such effort occurred. Therefore, the best course of action for this proceeding—one that has been effectively dormant for over six years—is for it to be discontinued, regardless of the proposal's potential merits.

This proceeding is just one example of why I believe Congress has directed the Board to issue quarterly reporting on all of its outstanding rulemaking proposals. We simply must do more to improve the timeliness of all Board actions.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2016–17883 Filed 7–27–16; 8:45 am]

BILLING CODE 4915–01–P

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[1] Under 49 CFR 1244.2, a railroad is required to file Waybill Sample information for all line-haul revenue waybills terminated on its lines if it terminated at least 4,500 revenue carloads in any of the three preceding years, or it terminated at least 5% of the revenue carloads terminating in any state in any of the three preceding years. The Board recognizes that some of the submitted information is commercially sensitive, and thus the Board's regulations place limitations on releasing Waybill Sample data. *See* 49 CFR 1244.9.

[2] Federal agencies view TIH movements as a potential target for terrorist activity and consider detailed information pertaining to TIH movements as sensitive security information (SSI). *See, e.g.*, Federal R.R. Admin. Order, Designation of Sensitive Security Information under 49 U.S.C. 40119(b), SSI Order 2011–06–FRA–01 (July 29, 2011), *http://www.stb.dot.gov/stb/industry/Rate_Cases.htm* (follow "Federal Railroad Administration, July 29, 2011" hyperlink).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

RIN 0648–XD649

Fisheries of the Exclusive Economic Zone Off Alaska; Groundfish Fisheries in the Gulf of Alaska; Reopening of Comment Period

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of intent to prepare an environmental impact statement; reopening of public comment period.

SUMMARY: NMFS, in consultation with the North Pacific Fishery Management Council (Council), announces its intent to expand the scope of an Environmental Impact Statement (EIS) for a new bycatch management program for trawl groundfish fisheries in the Gulf of Alaska (GOA). The bycatch management program for the GOA trawl groundfish fisheries would provide participants with incentives to effectively manage and reduce Chinook salmon and Pacific halibut bycatch and promote increased utilization of groundfish harvested in the GOA. NMFS previously published a notice of intent to prepare an EIS for the new bycatch management program on July 14, 2015. In June 2016, NMFS and the Council decided to reopen the comment period on the notice of intent to prepare an EIS because the Council and NMFS expanded scope of the EIS. NMFS will accept written comments from the public to identify issues of concern and assist the Council in determining the appropriate range of management alternatives for the EIS.

DATES: The comment period for the notice of intent published on July 14, 2015 (80 FR 40988) is reopened. Written comments will be accepted through September 26, 2016.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2014–0150, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2014-0150,* click the "Comment Now!" icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Glenn Merrill, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS, Attn: Ellen Sebastian. Mail comments to P.O. Box 21668, Juneau, AK 99802–1668.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter "N/A" in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Rachel Baker, (907) 586–7228 or email *rachel.baker@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Council is considering the establishment of a new bycatch management program for the GOA trawl groundfish fisheries. On July 14, 2015, NMFS announced its intent to prepare an EIS pursuant to the National Environmental Policy Act (NEPA) on the proposed bycatch management program (80 FR 40988). In the notice of intent, NMFS requested input from the public on the scope of the EIS, in addition to seeking comment for a range of reasonable alternatives and impacts to affected resources. NMFS received 36 public comments during the scoping period and provided a scoping report to the Council in October 2015. Based on the comments received on the July 14, 2015, notice of intent and on public input received by the Council at 10 of its meetings between October 2012 and June 2016, NMFS and the Council have decided to seek additional public input to assist them in determining the appropriate range of management alternatives for the EIS. The July 14, 2015, notice of intent provides additional detail on the GOA trawl groundfish fisheries and the proposed EIS (80 FR 40988).

NMFS and the Council have determined the preparation of an EIS may be required for the proposed action because some important aspects of the bycatch management program on target and bycatch species and their users may be uncertain or unknown and may result in significant impacts on the human environment not previously analyzed. NMFS and the Council are seeking information from the public through the EIS scoping process on the range of alternatives to be analyzed, and on the environmental, social, and economic issues to be considered in the analysis. Written comments generated during the previous scoping process and this scoping process will be provided to the Council and incorporated into the EIS for the proposed action.

Authority for the Proposed Action

Under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), the United States has exclusive fishery management authority over all fishery resources found within the exclusive economic zone (EEZ). The management of these fishery resources is vested in the Secretary of Commerce (Secretary). The Council has the responsibility to prepare fishery management plans for the fishery resources that require conservation and management in the EEZ off Alaska. Management of the Federal groundfish fisheries in the GOA is carried out under the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP). The FMP, its amendments, and implementing regulations (found at 50 CFR part 679) are developed in accordance with the requirements of the Magnuson-Stevens Act and other applicable Federal laws and executive orders, notably the NEPA and the Endangered Species Act (ESA).

Development of the Proposed Action

In October 2012, the Council unanimously adopted a purpose and need statement, and goals and objectives, to support the development of a proposed bycatch management program that would allocate exclusive harvest privileges for target groundfish species and prohibited species catch (PSC) to individuals, cooperatives, or other entities. Allocation of allowable harvests in the form of exclusive harvest privileges is a type of management approach that replaces the rigid management structure of a derby fishery with a flexible program that provides vessel-level accountability for harvests and removes disincentives to controlling and reducing bycatch and waste. Allocating exclusive harvest privileges to fishery participants can mitigate the potential negative impacts of a derby fishery on target and prohibited species, and on the operational and economic efficiency of the fisheries. In this type of management approach, a portion of the catch for a species (the exclusive harvest privilege) is allocated to individual fishermen, cooperatives, or other entities. Each participant in the fishery must have an exclusive harvest privilege, and each holder of harvest privileges must stop fishing when the holder's specific share of the quota is reached. The allocation of exclusive harvest privileges removes incentives for each participant to maximize catch rates to capture a larger share of the available catch before the fishery is closed. As a result, participants can make operational choices to improve fishing practices. These choices could include fishing in a slower and more efficient fashion, using modified gear with a lower harvest rate but which reduces bycatch, coordinating with other vessel operators to avoid areas of high bycatch, and processing fish in ways that yield increased value but which are possible only by slowing the pace of the fishery. This management approach allows fishermen to plan their fishing effort around the weather, markets, or other business considerations and allows other fishery dependent businesses to plan more effectively.

The Council has recommended and NMFS has implemented groundfish management programs in the EEZ off Alaska that allocate exclusive harvest privileges to fishery participants. These programs allocated a long-term exclusive harvest privilege to initially qualified participants for target groundfish species and PSC. The long-term exclusive harvest privilege yields an annual allocation of a portion of the TAC for target groundfish species and a portion of the applicable PSC limit. Based on experience with these programs, the Council and NMFS have determined that allocating exclusive harvest privileges of target groundfish species and PSC creates a structure for fishery participants to efficiently manage harvesting and processing activities that can result in reduced bycatch and improved utilization of groundfish fisheries. Additional information on these management programs is provided in the final rules implementing the American Fisheries Act in the Bering Sea (67 FR 79692, December 30, 2002), the Amendment 80 Program in the Bering Sea and Aleutian Islands (72 FR 52668, September 14, 2007), and the Rockfish Program in the Central GOA (76 FR 81248, December 27, 2011).

The Council continued to develop and refine its purpose and need and goals and objectives for a proposed bycatch management program for the GOA trawl groundfish fisheries at six of its meetings between October 2012 and October 2014. During this time period, the Council received testimony from stakeholders that the allocation of long-term exclusive harvest privileges can reduce opportunities for new participants to enter the fisheries. These stakeholders noted that the long-term exclusive harvest privileges allocated in previous management programs have acquired a high value as the overall value of the fishery increased. This has created a high cost of entry for new participants because they must purchase long-term exclusive harvest privileges to participate in the fisheries. The stakeholders indicated that the high cost of entry has resulted in economic barriers to new entry in these fisheries and requested that the Council consider measures to minimize these economic barriers in the proposed bycatch management program. The Council also received testimony indicating that the allocation of long-term harvest privileges can adversely impact fishery-dependent communities through fleet consolidation and changes in the distribution of fishery benefits.

In October 2015, the Council stated its intent to address concerns about potential economic barriers for new participants and adverse impacts on communities by including a new type of proposed bycatch management program that would allocate only PSC on an annual basis to individuals or cooperatives rather than allocating long-term exclusive harvest privileges for both target groundfish species and PSC. In June 2016, the Council identified an overarching goal and objective for the proposed bycatch management program to minimize economic barriers for new participants and maintain opportunities for entry into the trawl groundfish fisheries by limiting the type and duration of exclusive harvest privileges that may be allocated under the proposed bycatch management program. The Council also stated its intent to seek public input on additional mechanisms to limit exclusive harvesting privileges that may be allocated under the proposed bycatch management program to meet the Council's goals and objectives for the program.

Purpose and Need for the Proposed Action

The Council has identified the following purpose and need statement and goals and objectives for the proposed bycatch management program:

Purpose and Need Statement:

Management of Gulf of Alaska (GOA) groundfish trawl fisheries has grown increasingly complicated in recent years due to the implementation of measures to protect Steller sea lions and reduced Pacific halibut and Chinook salmon Prohibited Species Catch (PSC) limits under variable annual total allowable catch (TACs) limits for target groundfish species. These changes complicate effective management of target and non-target resources, and can have significant adverse social and economic impacts on harvesters, processors, and fishery-dependent GOA coastal communities.

The current management tools in the GOA Groundfish Fishery Management Plan (FMP) do not provide the GOA trawl fleet with the ability to effectively address these challenges, especially with regard to the fleet's ability to best reduce and utilize PSC. As such, the Council has determined that consideration of a new management regime for the GOA trawl fisheries is warranted.

The purpose of the proposed action is to create a new management structure which allocates prohibited species catch limits and/or allowable harvest to individuals, cooperatives, or other entities, which will mitigate the impacts of a derby-style race for fish. It is expected to improve stock conservation by creating vessel-level and/or cooperative-level incentives to eliminate wasteful fishing practices, provide mechanisms to control and reduce bycatch, and create accountability measures when utilizing PSC and/or target and secondary species. It will also increase at-sea monitoring in the GOA trawl fisheries, have the added benefit of reducing the incentive to fish during unsafe conditions, and improve operational efficiencies.

The Council recognizes that GOA harvesters, processors, and communities all have a stake in the groundfish trawl fisheries. The new program shall be designed to provide tools for the effective management and reduction of PSC and bycatch, and promote increased utilization of both target and secondary species harvested in the GOA. The program is also expected to increase the flexibility and economic efficiency of the GOA groundfish trawl fisheries and support the continued direct and indirect participation of the coastal communities that are dependent upon those fisheries. These management measures could apply to those species, or groups of species, harvested by trawl gear in the GOA, and/or to PSC. This program will not modify the overall management of other sectors in the GOA, or the Central GOA rockfish program, which already operates under a catch share system.

Overarching Goal and Objective:

The overarching goal of the Gulf of Alaska Trawl Bycatch Management program is to provide the fleet tools for the effective management and reduction of PSC and bycatch, and promote increased utilization of both target and secondary species while minimizing economic barriers for new participants by limiting harvest privileges that may be allocated (target species and/or prohibited species) in order to maintain opportunity for entry into the GOA trawl fisheries.

Goals and Objectives:

1. Balance the requirements of the National Standards in the Magnuson Stevens Act
2. Increase the ability of the groundfish trawl sector to avoid PSC species and utilize available amounts of PSC more efficiently by allowing groundfish trawl vessels to fish more slowly, strategically, and cooperatively, both amongst the vessels themselves and with shore-based processors
3. Reduce bycatch and regulatory discards by groundfish trawl vessels
4. Authorize fair and equitable access privileges that take into consideration the value of assets and investments in the fishery and dependency on and participation in the fishery for harvesters, processors, and communities
5. Balance interests of all sectors and provide equitable distribution of benefits and similar opportunities for increased value
6. Promote community stability and minimize adverse economic impacts by limiting consolidation, providing employment and entry opportunities, and increasing the economic viability of the groundfish harvesters, processors, and support industries
7. Improve the ability of the groundfish trawl sector to achieve Optimum Yield, including increased product retention, utilization, landings, and value by allowing vessels to choose the time and location of fishing to optimize returns and generate higher yields
8. Increase stability relative to the volume and timing of groundfish trawl landings, allowing processors to better plan operational needs as well as identify and exploit new products and markets
9. Increase safety by allowing trawl vessels to prosecute groundfish fisheries at slower speeds and in better conditions
10. Include measures for improved monitoring and reporting
11. Increase the trawl sector's ability to adapt to applicable Federal law (*i.e.*, Endangered Species Act)
12. Include methods to measure the success and impacts of all program elements
13. Minimize adverse impacts on sectors and areas not included in the program
14. Promote active participation by owners of harvest vessels and fishing privileges

Proposed Action

The proposed action to be analyzed in the EIS is a bycatch management program for the GOA trawl groundfish fisheries that would provide participants with incentives to effectively manage bycatch and reduce PSC, and that would promote increased utilization of groundfish harvested in the GOA. The proposed action is intended to improve stock conservation by imposing accountability measures for utilizing target and incidental catch and minimizing PSC to the extent practicable, creating incentives to eliminate wasteful fishing practices, providing mechanisms for participants to control and reduce bycatch in the trawl groundfish fisheries, and improving safety of life at sea and operational efficiencies. The proposed action would apply to participants in Federal groundfish fisheries prosecuted with trawl gear in the following areas: (1) The Western GOA Regulatory Area (Western GOA), (2) the Central GOA Regulatory Area (Central GOA), and (3) the West Yakutat District of the Eastern GOA Regulatory Area (West Yakutat District). These areas are defined at § 679.2 and shown in Figure 3 to 50 CFR part 679.

Alternatives

NMFS, in coordination with the Council, will evaluate a range of alternative bycatch management programs for the trawl groundfish fisheries in the Western GOA, Central GOA, and West Yakutat District. NMFS and the Council recognize that implementation of a GOA trawl bycatch management program would result in substantial changes to many of the current management measures for the GOA groundfish fisheries. The EIS will analyze these changes as well as alternative ways to manage target and incidental groundfish species and PSC in the GOA groundfish fisheries. The potential alternatives already identified for the bycatch management program are available on the Council's Web site at *http://www.npfmc.org/goa-trawl-bycatch-management/*. The following briefly summarizes the potential alternatives already identified for the EIS:

Alternative 1

Alternative 1 is the no action alternative (status quo). The Council and NMFS annually establish biological thresholds and annual total allowable catch limits for groundfish species to sustainably manage the groundfish fisheries in the GOA. The Council and NMFS implemented the license limitation program (LLP), which limits access to the groundfish fisheries in the GOA. The groundfish LLP requires each vessel in the GOA to have an LLP license on board the vessel at all times while directed fishing for license limitation groundfish, with limited exemptions. The preamble to the final rule implementing the groundfish LLP provides a more detailed explanation of the rationale for specific provisions in the LLP (October 1, 1998; 63 FR 52642).

While the LLP limits the total number of vessels that can participate in the GOA groundfish fisheries, it does not limit harvest by individual vessels or assign exclusive harvest privileges to specific vessels or entities. This has led to a competitive derby fishery in the GOA groundfish fisheries, in which fishermen race against each other to harvest as much fish as they can before the annual catch limit or the PSC limit is reached and the fishery is closed for the season. A derby fishery relies on a fairly rigid management structure that is not adaptable to changes in weather, markets, or other operating considerations. Therefore, a derby fishery often results in shorter fishing seasons and unsafe fishing practices. It can also create a substantial disincentive for participants to take actions to reduce bycatch use and waste, particularly if those actions could reduce groundfish catch rates. In a derby fishery, participants who choose not to take actions to reduce bycatch and waste stand to gain additional groundfish catch by continuing to harvest at a higher bycatch rate, at the expense of any vessels engaged in bycatch avoidance.

The Council has designated Pacific salmon and Pacific halibut, along with several other species (Pacific herring, steelhead trout, king crab, and Tanner crab) as prohibited species in the GOA groundfish fisheries. Prohibited species are species taken incidentally in the groundfish trawl fisheries and designated as "prohibited species" because they are target species in other, fully utilized domestic fisheries. The Council has recommended and NMFS has implemented various measures to control the catch of such prohibited species in GOA groundfish fisheries. Prohibited species incidentally caught while directed fishing for groundfish in the GOA may not be sold or kept for personal use and must be discarded with a minimum of injury. In addition, the GOA groundfish fishery restrictions include PSC limits for Chinook salmon and Pacific halibut to constrain the amount of bycatch of these species in the groundfish fisheries. When harvest of prohibited species in a groundfish fishery reaches the specified PSC limit for that fishery, NMFS closes directed fishing for the target groundfish species, even if the total allowable catch limit for that target groundfish species has not been fully harvested.

Alternative 2

Alternative 2 is a bycatch management program that would allocate exclusive harvest privileges to participants in the Western GOA, Central GOA, and West Yakutat District trawl groundfish fisheries who voluntarily join a cooperative. Participants who do not choose to join a cooperative would have the opportunity to participate in the current limited access management system under the groundfish LLP. In Alternative 2, the Council is considering allocating exclusive harvest privileges for target groundfish species and Chinook salmon and Pacific halibut PSC to cooperatives. Alternative 2 contains several elements and options for determining eligible participants, groundfish species and PSC to be allocated, and methods for determining allocations to cooperatives and the limited access fishery. Alternative 2 includes elements and options for cooperative formation and membership that are intended to provide incentives for participation by harvesters and processors to improve coordination and operational efficiencies. Alternative 2 also contains a number of elements that are intended to provide for fishery dependent community stability, such as harvest privilege consolidation limits and area- and port-specific delivery requirements.

Alternative 3

Alternative 3 is a bycatch management program that would allocate Chinook salmon and Pacific halibut PSC to participants in the Western GOA, Central GOA, and West Yakutat District trawl groundfish fisheries who voluntarily join a cooperative. Participants who do not choose to join a cooperative would have the opportunity to participate in the current limited access management system under the groundfish LLP. Alternative 3 contains several elements and options for determining eligible participants and methods for determining PSC allocations to cooperatives and the limited access management fishery. Alternative 3 also includes elements and options for cooperative formation and membership that are intended to provide incentives for participation by harvesters and processors to improve coordination and operational efficiencies.

Alternative 4

Alternative 4 is a bycatch management program that would allocate exclusive harvest privileges to fishery participants who voluntarily join a cooperative under Alternative 2 and either (1) a Community Fishing Association as defined in section 303A(c)(3) of the Magnuson-Stevens Act or (2) an Adaptive Management Program. Participants who do not choose to join a cooperative would have the opportunity to participate in the current limited access management system under the groundfish LLP. In Alternative 4, the Council is considering allocating exclusive harvest privileges for target groundfish species and PSC to cooperatives and either a Community Fishing Association or to persons who meet the criteria established for an Adaptive Management Program. The allocation to a Community Fishing Association or Adaptive Management Program would meet objectives that include providing for sustained participation of fishing communities, promoting conservation measures, and assisting vessel owner-operators, captains, and crew who want to enter and participate in the GOA trawl groundfish fisheries.

Public Involvement

Scoping is an early and open process for determining the scope of issues to be addressed in an EIS and for identifying the significant issues related to the proposed action. A principal objective of the scoping and public involvement process is to identify a range of reasonable management alternatives that, with adequate analysis, will delineate critical issues and provide a clear basis for distinguishing among those alternatives and selecting a preferred alternative. Through this notice, NMFS is reopening the comment period on scoping for the EIS for the proposed bycatch management program so that interested or affected people may participate and contribute to the final decision.

NMFS is reopening the comment period to seek written public comments on the scope of issues, including potential impacts, and alternatives that should be considered for a bycatch management program for the trawl groundfish fisheries in the Western GOA, Central GOA, and West Yakutat District of the GOA. NMFS will consider written public comments received during this scoping process, as well as those received during the scoping process from July 14, 2015, through August 28, 2015 (80 FR 40988), and provide the Council with a summary of all written comments received to assist the Council in determining the appropriate range of management alternatives for the EIS. Written comments should be as specific as possible to be the most helpful. Written comments received during the scoping process, including the names and addresses of those submitting them, will be considered part of the public record of the proposed action and will be available for public inspection. Written comments will be accepted at the address above (see **ADDRESSES**). Please visit the NMFS Alaska Region Web site at *http://www.alaskafisheries.noaa.gov* for more information on the GOA trawl bycatch management program EIS and for guidance on submitting effective written public comments.

The public is invited to participate and provide input at Council meetings where the latest scientific information regarding the GOA groundfish fisheries is reviewed and alternative bycatch management programs are developed and evaluated. Notice of future Council meetings will be published in the **Federal Register** and on the Internet at *http://www.npfmc.org/*. Please visit this Web site for information and guidance on participating in Council meetings. Additional information on the Council's development of the GOA trawl bycatch management program is available at *http://www.npfmc.org/goa-trawl-bycatch-management/*.

Authority: 16 U.S.C. 1801 *et. seq.*

Dated: July 25, 2016.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–17879 Filed 7–27–16; 8:45 am]

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Notices

Federal Register
Vol. 81, No. 145
Thursday, July 28, 2016

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the New Mexico Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meetings.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a planning meeting of the New Mexico Advisory Committee to the Commission will convene at 11:00 a.m. (MDT) on Thursday, August 4, 2016, via teleconference. The purpose of the meeting is to review and comment on transcript of the June 24, 2016 briefing meeting on Elder Abuse. The committee will also discuss next steps for the project.

Members of the public may listen to the discussion by dialing the following Conference Call Toll-Free Number: 1–888–481–2844; Conference ID: 7748208. Please be advised that before being placed into the conference call, the operator will ask callers to provide their names, their organizational affiliations (if any), and an email address (if available) prior to placing callers into the conference room. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free phone number.

Persons with hearing impairments may also follow the discussion by first calling the Federal Relay Service (FRS) at 1–800–977–8339 and provide the FRS operator with the Conference Call Toll-Free Number: 1–888–481–2844, Conference ID: 7748208. Members of the public are invited to submit written comments; the comments must be received in the regional office by Monday, September 5, 2016. Written comments may be mailed to the Rocky Mountain Regional Office, U.S. Commission on Civil Rights, 1961 Stout Street, Suite 13–201, Denver, CO 80294, faxed to (303) 866–1050, or emailed to Evelyn Bohor at *ebohor@usccr.gov.* Persons who desire additional information may contact the Rocky Mountain Regional Office at (303) 866–1040.

Records and documents discussed during the meeting will be available for public viewing as they become available at *https://database.faca.gov/committee/meetings.aspx?cid=264* and clicking on the "Meeting Details" and "Documents" links. Records generated from this meeting may also be inspected and reproduced at the Rocky Mountain Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission's Web site, *www.usccr.gov,* or to contact the Rocky Mountain Regional Office at the above phone number, email or street address.

AGENDA:

- Welcome and Roll-call
  Sandra Rodriguez, Chair, New Mexico Advisory Committee
  Malee V. Craft, Regional Director, Rocky Mountain Regional Office (RMRO)
- Review and receive comments on transcript of June 24, 2016 briefing meeting on Elder Abuse
- Next Steps

DATES: Thursday, August 4, 2016, at 11:00 a.m. (MDT)

ADDRESSES: To be held via teleconference:

Conference Call Toll-Free Number: 1–888–481–2844, Conference ID: 7748208.

TDD: Dial Federal Relay Service 1–800–977–8339 and give the operator the above conference call number and conference ID.

FOR FURTHER INFORMATION CONTACT: Malee V. Craft, DFO, *mcraft@usccr.gov,* 303–866–1040.

Exceptional Circumstance: Pursuant to 41 CFR 102–3.150, the notice for this meeting is given less than 15 calendar days prior to the meeting because of the exceptional circumstances of an administrative exceptional circumstance. Given the exceptional urgency of the events, the agency and advisory committee deem it important for the advisory committee to meet on the date given.

Dated: July 22, 2016.

David Mussatt,

Chief, Regional Programs Unit.

[FR Doc. 2016–17817 Filed 7–27–16; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–47–2016]

Foreign-Trade Zone (FTZ) 249—Pensacola, Florida; Notification of Proposed Production Activity GE Renewables North America, LLC, Subzone 249A, (Wind Turbine Nacelles, Hubs, and Drivetrains), Pensacola, Florida

GE Renewables North America, LLC (GE Renewables) submitted a notification of proposed production activity to the FTZ Board for its facility in Pensacola, Florida within Subzone 249A. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on July 22, 2016.

GE Renewables already has authority to produce wind turbines and related hubs and nacelles within Subzone 249A and also has a request pending to add foreign status materials/components to the scope of authority (Doc. B–41–2016). The current request would add a finished product and foreign status materials/components to the scope of authority. Pursuant to 15 CFR 400.14(b), additional FTZ authority would be limited to the specific foreign-status materials/components and specific finished products described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt GE Renewables from customs duty payments on the foreign-status materials/components used in export production. On its domestic sales, GE Renewables would be able to choose the duty rates during customs entry procedures that apply to: wind turbines and related hubs and nacelles; and, repower drivetrain assemblies (duty-free or 2.5%) for the foreign-status materials/components noted below and in the existing scope of authority. Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

The materials/components sourced from abroad include the following repower drivetrain components: Brake calipers; brake hydraulic power units; gearboxes; main bearings; main shafts; and, pillow blocks (duty rate ranges from duty-free to 5.8%).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is September 6, 2016.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the "Reading Room" section of the Board's Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Elizabeth Whiteman at *Elizabeth.Whiteman@trade.gov* or (202) 482–0473.

Dated: July 25, 2016.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2016–17892 Filed 7–27–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–46–2016]

Foreign-Trade Zone (FTZ) 189—Kent/Ottawa/Muskegon Counties, Michigan; Notification of Proposed Production Activity; Adient US LLC; Subzone 189D (Motorized Seat Adjusters for Motor Vehicles); Holland and Zeeland, Michigan

Adient US LLC (Adient), owned by Johnson Controls, Inc., submitted a notification of proposed production activity to the FTZ Board for its facilities within FTZ 189D, at sites in Holland and Zeeland, Michigan. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on July 13, 2016.

The facilities are used for the production of motorized seat adjusters for motor vehicles. Pursuant to 15 CFR 400.14(b), FTZ activity would be limited to the specific foreign-status components and specific finished product described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt Adient from customs duty payments on the foreign-status components used in export production. On its domestic sales, Adient would be able to choose the duty rate during customs entry procedures that applies to motorized seat adjusters (duty free) for the foreign-status electric seat adjuster motors (duty rate—2.8%). Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary at the address below. The closing period for their receipt is September 6, 2016.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the "Reading Room" section of the FTZ Board's Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Diane Finver at *Diane.Finver@trade.gov* or (202) 482–1367.

Dated: July 21, 2016.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2016–17807 Filed 7–27–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–50–2016]

Approval of Subzone Status—Flemish Master Weavers—Sanford, Maine

On April 21, 2016, the Executive Secretary of the Foreign-Trade Zones (FTZ) Board docketed an application submitted by the City of Waterville, grantee of FTZ 186, requesting subzone status subject to the existing activation limit of FTZ 186, on behalf of Flemish Master Weavers in Sanford, Maine.

The application was processed in accordance with the FTZ Act and Regulations, including notice in the **Federal Register** inviting public comment (81 FR 25374–25375, 04–28–2016). The FTZ staff examiner reviewed the application and determined that it meets the criteria for approval. Pursuant to the authority delegated to the FTZ Board's Executive Secretary (15 CFR 400.36(f)), the application to establish Subzone 186A is approved, subject to the FTZ Act and the Board's regulations, including section 400.13, and further subject to FTZ 186's 2,000-acre activation limit.

Dated: July 22, 2016.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2016–17891 Filed 7–27–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–871, A–475–835, A–469–815]

Finished Carbon Steel Flanges From India, Italy, and Spain: Initiation of Less-Than-Fair-Value Investigations

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* July 20, 2016.

FOR FURTHER INFORMATION CONTACT: Fred Baker at (202) 482–2924 (India); Moses Song or Edythe Artman at (202) 482–5041 or (202) 482–3931, respectively (Italy); and Michael Heaney at (202) 482–4475 (Spain), AD/CVD Operations, Enforcement and Compliance, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

The Petitions

On June 30, 2016, the Department of Commerce (the Department) received antidumping duty (AD) petitions concerning imports of finished carbon steel flanges (steel flanges) from India, Italy, and Spain, filed in proper form on behalf of Weldbend Corporation and Boltex Mfg. Co., L.P. (Petitioners).[1] The Petitions were accompanied by a countervailing duty (CVD) petition on steel flanges from India.[2] Petitioners are domestic producers of steel flanges.[3]

On July 6, 8, and 12, 2016, the Department requested additional information and clarification of certain areas of the Petitions.[4] Petitioners filed

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[1] *See* Petitions for the Imposition of Antidumping Duties on Imports of Finished Carbon Steel Flanges from India, Italy and Spain and Countervailing Duties on Imports from India, dated June 30, 2016 (the Petitions).

[2] *Id.*

[3] *See* Volume I of the Petitions, at 2, and Exhibit I–15.

[4] *See* Letter from the Department to Petitioners entitled "Petitions for the Imposition of Antidumping Duties on Imports of Finished Carbon Steel Flanges from India, Italy, and Spain and Countervailing Duties on Imports from India: Supplemental Questions," dated July 6, 2016 (General Issues Supplemental Questionnaire); *see also* Letter from the Department to Petitioners entitled "Petition for the Imposition of Antidumping Duties on Imports of Finished Carbon Steel Flanges from India: Supplemental Questions," dated July 6, 2016 (India Supplemental Questionnaire); *see also* Letter from the Department

Continued

responses to these requests on July 8 and 13, 2016, respectively.[5]

In accordance with section 732(b) of the Tariff Act of 1930, as amended (the Act), Petitioners allege that imports of steel flanges from India, Italy, and Spain are being, or are likely to be, sold in the United States at less-than-fair value within the meaning of section 731 of the Act, and that such imports are materially injuring, or threatening material injury to, an industry in the United States. Also, consistent with section 732(b)(1) of the Act, the Petitions are accompanied by information reasonably available to Petitioners supporting their allegations.

The Department finds that Petitioners filed these Petitions on behalf of the domestic industry because Petitioners are interested parties as defined in section 771(9)(C) of the Act. The Department also finds that Petitioners demonstrated sufficient industry support with respect to the initiation of the AD investigations that Petitioners are requesting.[6]

Period of Investigation

Because the Petitions were filed on June 30, 2016, the period of investigation (POI) for each investigation is, pursuant to 19 CFR 351.204(b)(1), April 1, 2015, through March 31, 2016.

Scope of the Investigations

The product covered by these investigations is steel flanges from India, Italy, and Spain. For a full description of the scope of these investigations, *see* the "Scope of the Investigations," at Appendix I of this notice.

Comments on Scope of the Investigations

During our review of the Petitions, the Department issued questions to, and received responses from, Petitioners pertaining to the proposed scope to ensure that the scope language in the Petitions would be an accurate reflection of the products for which the domestic industry is seeking relief.[7]

As discussed in the preamble to the Department's regulations, we are setting aside a period for interested parties to raise issues regarding product coverage (scope). The Department will consider all comments received from parties and, if necessary, will consult with parties prior to the issuance of the preliminary determinations. If scope comments include factual information (*see* 19 CFR 351.102(b)(21)), all such factual information should be limited to public information. In order to facilitate preparation of its questionnaires, the Department requests all interested parties to submit such comments by 5:00 p.m. Eastern Daylight Time (EDT) on August 9, 2016, which is 20 calendar days from the signature date of this notice. Any rebuttal comments, which may include factual information, must be filed by 5:00 p.m. EDT on August 19, 2016, which is 10 calendar days after the initial comments.

The Department requests that any factual information the parties consider relevant to the scope of the investigations be submitted during this time period. However, if a party subsequently finds that additional factual information pertaining to the scope of the investigations may be relevant, the party may contact the Department and request permission to submit the additional information. All such comments must be filed on the records of each of the concurrent AD and CVD investigations.

Filing Requirements

All submissions to the Department must be filed electronically using Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS).[8] An electronically filed document must be received successfully in its entirety by the time and date when it is due. Documents excepted from the electronic submission requirements must be filed manually (*i.e.*, in paper form) with Enforcement and Compliance's APO/Dockets Unit, Room 18022, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, and stamped with the date and time of receipt by the applicable deadlines.

Comments on Product Characteristics for AD Questionnaires

The Department will be giving interested parties an opportunity to provide comments on the appropriate physical characteristics of steel flanges to be reported in response to the Department's AD questionnaires. This information will be used to identify the key physical characteristics of the merchandise under consideration in order to report the relevant costs of production accurately as well as to develop appropriate product-comparison criteria.

Interested parties may provide any information or comments that they feel are relevant to the development of an accurate list of physical characteristics. Specifically, they may provide comments as to which characteristics are appropriate to use as: (1) General product characteristics and (2) product-comparison criteria. We note that it is not always appropriate to use all product characteristics as product-comparison criteria. We base product-comparison criteria on meaningful

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to Petitioners entitled "Petition for the Imposition of Antidumping Duties on Imports of Finished Carbon Steel Flanges from Italy: Supplemental Questions," dated July 6, 2016 (Italy Supplemental Questionnaire); *see also* Letter from the Department to Petitioners entitled "Petition for the Imposition of Antidumping Duties on Imports of Finished Carbon Steel Flanges from Spain: Supplemental Questions," dated July 6, 2016 (Spain Supplemental Questionnaire); *see also* Letter from the Department to Petitioners entitled "Petitions for the Imposition of Antidumping Duties on Imports of Finished Carbon Steel Flanges from India, Italy, and Spain and Countervailing Duties on Imports from India: Supplemental Questions," dated July 8, 2016 (Second General Issues Supplemental Questionnaire); *see also* Letter from the Department to Petitioners entitled "Petition for the Imposition of Antidumping Duties on Imports of Finished Carbon Steel Flanges from Italy: Supplemental Questions," dated July 12, 2016 (Italy Second Supplemental Questionnaire); *see also* Letter from the Department to Petitioners entitled "Petition for the Imposition of Antidumping Duties on Imports of Finished Carbon Steel Flanges from Italy: Supplemental Questions," dated July 12, 2016 (Spain Second Supplemental Questionnaire).

[5] *See* Letter from Petitioner to the Department entitled "Re: Finished Carbon Steel Flanges from India, Italy and Spain: Supplemental Questionnaire Response Regarding the Antidumping Petition—General Questions," dated July 8, 2016 (General Issues Supplement); *see also* Letter from Petitioner to the Department entitled "Re: Finished Carbon Steel Flanges from India: Supplemental Questionnaire Response Regarding the Antidumping Petition—General Questions," dated July 8, 2016 (India Supplement); *see also* Letter from Petitioner to the Department entitled "Re: Finished Carbon Steel Flanges from Italy: Supplemental Questionnaire Response Regarding the Antidumping Petition—General Questions," dated July 8, 2016 (Italy Supplement); *see also* Letter from Petitioner to the Department entitled "Re: Finished Carbon Steel Flanges from Spain: Supplemental Questionnaire Response Regarding the Antidumping Petition—General Questions," dated July 8, 2016 (Spain Supplement); *see also* Letter from Petitioner to the Department entitled "Re: Finished Carbon Steel Flanges from India, Italy and Spain: 2nd Supplemental Questions Response," dated July 13, 2016 (Second General Issues Supplement) *see also* Letter from Petitioner to the Department entitled "Re: Finished Carbon Steel Flanges from Italy: 2nd Supplemental Questionnaire Response," dated July 8, 2016 (Italy Second Supplement); *see also* Letter from Petitioner to the Department entitled "Re: Finished Carbon Steel Flanges from Spain: 2nd Supplemental Questionnaire Response," dated July 8, 2016 (Spain Second Supplement).

[6] *See* the "Determination of Industry Support for the Petitions" section below.

[7] *See* General Issues Supplemental Questionnaire and Second General Issues Supplemental Questionnaire; *see also* General Issues Supplement and Second General Issues Supplement.

[8] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011) for details of the Department's electronic filing requirements, which went into effect on August 5, 2011. Information on help using ACCESS can be found at *https://access.trade.gov/help.aspx* and a handbook can be found at *https://access.trade.gov/help/Handbook%20on%20Electronic%20Filling%20Procedures.pdf.*

commercial differences among products. In other words, although there may be some physical product characteristics utilized by manufacturers to describe steel flanges, it may be that only a select few product characteristics take into account commercially meaningful physical characteristics. In addition, interested parties may comment on the order in which the physical characteristics should be used in matching products. Generally, the Department attempts to list the most important physical characteristics first and the least important characteristics last.

In order to consider the suggestions of interested parties in developing and issuing the AD questionnaires, all comments must be filed by 5:00 p.m. EDT on August 9, 2016, which is 20 calendar days from the signature date of this notice. Any rebuttal comments must be filed by 5:00 p.m. EDT on August 19, 2016. All comments and submissions to the Department must be filed electronically using ACCESS, as explained above, on the records of the India, Italy, and Spain less-than-fair-value investigations, as well as the India countervailing duty investigation.

Determination of Industry Support for the Petitions

Section 732(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 732(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) At least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 732(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, the Department shall: (i) Poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the "industry."

Section 771(4)(A) of the Act defines the "industry" as the producers as a whole of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs the Department to look to producers and workers who produce the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether "the domestic industry" has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both the Department and the ITC must apply the same statutory definition regarding the domestic like product,[9] they do so for different purposes and pursuant to a separate and distinct authority. In addition, the Department's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law.[10]

Section 771(10) of the Act defines the domestic like product as "a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title." Thus, the reference point from which the domestic like product analysis begins is "the article subject to an investigation" (*i.e.*, the class or kind of merchandise to be investigated, which normally will be the scope as defined in the Petitions).

With regard to the domestic like product, Petitioners do not offer a definition of the domestic like product distinct from the scope of the investigations. Based on our analysis of the information submitted on the record, we have determined that steel flanges constitute a single domestic like product and we have analyzed industry support in terms of that domestic like product.[11]

In determining whether Petitioners have standing under section 732(c)(4)(A) of the Act, we considered the industry support data contained in the Petitions with reference to the domestic like product as defined in the "Scope of the Investigations," in Appendix I of this notice. Petitioners provided their production of the domestic like product in 2015,[12] as well as an estimate of the total 2015 production of the domestic like product for the entire domestic industry.[13] To establish industry support, Petitioners compared their own production to the estimated total production of the domestic like product for the entire domestic industry.[14]

Our review of the data provided in the Petitions and other information readily available to the Department indicates that Petitioners have established industry support.[15] First, the Petitions established support from domestic producers (or workers) accounting for more than 50 percent of the total production of the domestic like product and, as such, the Department is not required to take further action in order to evaluate industry support (*e.g.*, polling).[16] Second, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(i) of the Act because the domestic producers (or workers) who support the Petitions account for at least 25 percent of the total production of the domestic like product.[17] Finally, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(ii) of the Act because the domestic producers (or workers) who support the Petitions account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petitions.[18] Accordingly, the Department determines that the Petitions were filed on behalf of the domestic industry within the meaning of section 732(b)(1) of the Act.

The Department finds that Petitioners filed the Petitions on behalf of the domestic industry because they are interested parties as defined in section 771(9)(C) of the Act and they have demonstrated sufficient industry support with respect to the AD investigations that they are requesting the Department initiate.[19]

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[9] *See* section 771(10) of the Act.

[10] *See USEC, Inc.* v. *United States,* 132 F. Supp. 2d 1, 8 (CIT 2001) (citing *Algoma Steel Corp., Ltd.* v. *United States,* 688 F. Supp. 639, 644 (CIT 1988), *aff'd* 865 F.2d 240 (Fed. Cir. 1989)).

[11] For a discussion of the domestic like product analysis in this case, *see* Antidumping Duty Investigation Initiation Checklist: Finished Carbon Steel Flanges from India (India AD Initiation Checklist), at Attachment II, Analysis of Industry Support for the Antidumping and Countervailing Duty Petitions Covering Finished Carbon Steel Flanges from India, Italy, and Spain (Attachment II); Antidumping Duty Investigation Initiation Checklist: Finished Carbon Steel Flanges from Italy (Italy AD Initiation Checklist), at Attachment II; and Antidumping Duty Investigation Initiation Checklist: Finished Carbon Steel Flanges from Spain (Spain AD Initiation Checklist), at Attachment II. These checklists are dated concurrently with this notice and on file electronically via ACCESS. Access to documents filed via ACCESS is also available in the Central Records Unit, Room B8024 of the main Department of Commerce building.

[12] *See* Volume I of the Petitions, at Exhibits I–15–A and I–15–B.

[13] *See* Volume I of the Petitions, at Exhibit I–15.

[14] *Id.*

[15] *See* India AD Initiation Checklist, Italy AD Initiation Checklist, and Spain AD Initiation Checklist, at Attachment II.

[16] *See* section 732(c)(4)(D) of the Act; *see also* India AD Initiation Checklist, Italy AD Initiation Checklist, and Spain AD Initiation Checklist, at Attachment II.

[17] *See* India AD Initiation Checklist, Italy AD Initiation Checklist, and Spain AD Initiation Checklist, at Attachment II.

[18] *Id.*

Allegations and Evidence of Material Injury and Causation

Petitioners allege that the U.S. industry producing the domestic like product is being materially injured, or is threatened with material injury, by reason of the imports of the subject merchandise sold at less than normal value (NV). In addition, Petitioners allege that subject imports exceed the negligibility threshold provided for under section 771(24)(A) of the Act.[20]

Petitioners contend that the industry's injured condition is illustrated by reduced market share, underselling and price suppression or depression, lost sales and revenues, declines in production, capacity utilization, and U.S. shipments, negative impact on employment variables, and decline in financial performance.[21] We have assessed the allegations and supporting evidence regarding material injury, threat of material injury, and causation, and we have determined that these allegations are properly supported by adequate evidence, and meet the statutory requirements for initiation.[22]

Allegations of Sales at Less-Than-Fair Value

The following is a description of the allegations of sales at less-than-fair value upon which the Department based its decision to initiate investigations of imports of steel flanges from India, Italy, and Spain. The sources of data for the deductions and adjustments relating to U.S. price and NV are discussed in greater detail in the country-specific initiation checklists.

Export Price

For India, Italy, and Spain, Petitioners based export price (EP) U.S. prices on average unit values (AUVs) calculated using publicly available import statistics from the ITC's Dataweb for each country under the relevant Harmonized Tariff Schedule of the United States (HTSUS) subheadings for steel flanges.[23] To calculate ex-factory prices, Petitioners made deductions from U.S. price for movement expenses, consistent with the manner in which the data is reported in Dataweb.[24]

Normal Value

For India and Italy, Petitioners provided home market price information obtained through market research for steel flanges produced and offered for sale in India and Italy,[25] and supported this information with an affidavit or declaration from a market researcher for the price information.[26] Petitioners made no adjustments to the India or Italy offer price to calculate NV, as none were warranted by the terms associated with the offers.[27]

Normal Value Based on Constructed Value

Pursuant to section 773(b)(3) of the Act, COP consists of the cost of manufacturing (COM), SG&A expenses, financial expenses, and packing expenses. Petitioners calculated COM based on Petitioners' experience, adjusted for known differences between producing in the United States and producing in the respective country (*i.e.,* Italy and Spain), during the proposed POI.[28] Using publicly-available data to account for price differences, Petitioners multiplied the surrogate usage quantities by the submitted value of the inputs used to manufacture steel flanges in each country.[29] For Italy and Spain, labor rates were derived from publicly available sources multiplied by the product-specific usage rates.[30] For Italy and Spain, to determine factory overhead, SG&A, and financial expense rates, Petitioners relied on financial statements of companies that were producers of identical or comparable merchandise operating in the respective foreign country.[31]

For Italy, pursuant to sections 773(a)(4), 773(b), and 773(e) of the Act, Petitioners provided information that sales of steel flanges in the home market were made at prices below the cost of production (COP) and also calculated NV based on constructed value (CV).[32]

For Spain, Petitioners were unable to obtain home market prices and, pursuant to sections 773(a)(4), 773(b) and 773(e) of the Act, calculated NV based on CV.[33] Pursuant to section 773(e) of the Act, CV consists of the COM, SG&A expenses, financial expenses, packing expenses, and profit. Petitioners calculated CV using the same average COM, SG&A expenses, and financial expenses, used to calculate COP.[34] Petitioners relied on the financial statements of the same producers that they used for calculating manufacturing overhead, SG&A expenses, and financial expenses to calculate the profit rate.[35]

Fair Value Comparisons

Based on the data provided by Petitioners, there is reason to believe that imports of steel flanges from India, Italy, and Spain, are being, or are likely to be, sold in the United States at less-than-fair value. Based on comparisons of EP to NV in accordance with section 773(a) of the Act, the estimated dumping margin(s) for steel flanges are as follows: (1) India ranges from 17.80 to 37.84 percent;[36] (2) Italy ranges from 15.76 percent to 204.53 percent;[37] and (3) Spain ranges from 13.19 percent to 24.43 percent.[38]

Initiation of Less-Than-Fair-Value Investigations

Based upon the examination of the AD Petitions on steel flanges from India, Italy, and Spain, we find that Petitions meet the requirements of section 732 of the Act. Therefore, we are initiating AD investigations to determine whether imports of steel flanges for India, Italy, and Spain are being, or are likely to be, sold in the United States at less-than-fair value. In accordance with section 733(b)(1)(A) of the Act and 19 CFR 351.205(b)(1), unless postponed, we will make our preliminary determinations no later than 140 days after the date of this initiation.

On June 29, 2015, the President of the United States signed into law the Trade Preferences Extension Act of 2015, which made numerous amendments to the AD and CVD law.[39] The 2015 law does not specify dates of application for those amendments. On August 6, 2015, the Department published an interpretative rule, in which it announced the applicability dates for each amendment to the Act, except for amendments contained in section 771(7) of the Act, which relate to determinations of material injury by the ITC.[40] The amendments to sections 771(15), 773, 776, and 782 of the Act are applicable to all determinations made on or after August 6, 2015, and, therefore, apply to these AD investigations.[41]

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[19] *See* India AD Initiation Checklist, Italy AD Initiation Checklist, and Spain AD Initiation Checklist, at Attachment II.

[20] *See* Volume I of the Petitions, at 18–19; *see also* General Issues Supplement, at 6 and Exhibit 3.

[21] *See* Volume I of the Petitions, at 12–16, 18–34 and Exhibits I–2, I–9 and I–11 through I–14; *see also* General Issues Supplement, at 6 and Exhibit 3.

[22] *See* India AD Checklist, at Attachment III, Analysis of Allegations and Evidence of Material Injury and Causation for the Antidumping and Countervailing Duty Petitions Covering Finished Carbon Steel Flanges from the India, Italy, and Spain (Attachment III); *see also* Italy AD Checklist, at Attachment III; and Spain AD Checklist, at Attachment III.

[23] *See* India AD Checklist, Italy AD Checklist, and Spain AD Checklist.

[24] *Id.*

[25] *See* India AD Checklist and Italy AD Checklist.

[26] *See* India AD Checklist, Italy AD Checklist, and Spain AD Checklist.

[27] *See* India AD Checklist and Italy AD Checklist.

[28] *See* Italy AD Checklist and Spain AD Checklist.

[29] *See* Italy AD Checklist and Spain AD Checklist.

[30] *Id.*

[31] *Id.*

[32] *See* Italy AD Checklist.

[33] *See* Spain AD Checklist.

[34] *See* Italy AD Checklist and Spain AD Checklist.

[35] *Id.*

[36] *See* India AD Checklist.

[37] *See* Italy AD Checklist.

[38] *See* Spain AD Checklist.

[39] *See* Trade Preferences Extension Act of 2015, Public Law 114–27, 129 Stat. 362 (2015).

Respondent Selection

Petitioners named 31 companies in India, 26 companies in Italy, and 6 companies in Spain as producers/exporters of steel flanges.[42] Following standard practice in AD investigations involving market economy countries, in the event the Department determines that the number of companies is large and it cannot individually examine each company based upon the Department's resources, where appropriate, the Department intends to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports under the appropriate Harmonized Tariff Schedule of the United States numbers listed with the scope in Appendix I, below. We also intend to release the CBP data under Administrative Protective Order (APO) to all parties with access to information protected by APO on the record within five business days of publication of this **Federal Register** notice. Comments regarding the CBP data and respondent selection should be submitted seven calendar days after the placement of the CBP data on the record of these investigations. Parties wishing to submit rebuttal comments should submit those comments five calendar days after the deadline for the initial comments.

Comments for the above-referenced investigations must be filed electronically using ACCESS. An electronically-filed document must be received successfully in its entirety by the Department's electronic records system, ACCESS, by 5:00 p.m. EDT by the dates noted above. We intend to make our decision regarding respondent selection within 20 days of publication of this notice.

Distribution of Copies of the Petitions

In accordance with section 732(b)(3)(A) of the Act and 19 CFR 351.202(f), copies of the public version of the Petitions have been provided to the governments of India, Italy, and Spain via ACCESS. To the extent practicable, we will attempt to provide a copy of the public version of the Petitions to each exporter named in the Petitions, as provided under 19 CFR 351.203(c)(2).

ITC Notification

We will notify the ITC of our initiation, as required by section 732(d) of the Act.

Preliminary Determinations by the ITC

The ITC will preliminarily determine, within 45 days after the date on which the Petitions were filed, whether there is a reasonable indication that imports of steel flanges from India, Italy, and Spain are materially injuring or threatening material injury to a U.S. industry.[43] A negative ITC determination for any country will result in the investigation being terminated with respect to that country;[44] otherwise, these investigations will proceed according to statutory and regulatory time limits.

Submission of Factual Information

Factual information is defined in 19 CFR 351.102(b)(21) as: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by the Department; and (v) evidence other than factual information described in (i)–(iv). Any party, when submitting factual information, must specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct. Time limits for the submission of factual information are addressed in 19 CFR 351.301, which provides specific time limits based on the type of factual information being submitted. Please review the regulations prior to submitting factual information in these investigations.

Extensions of Time Limits

Parties may request an extension of time limits before the expiration of a time limit established under part 351, or as otherwise specified by the Secretary. In general, an extension request will be considered untimely if it is filed after the expiration of the time limit established under part 351 expires. For submissions that are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. on the due date. Under certain circumstances, we may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, we will inform parties in the letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. An extension request must be made in a separate, stand-alone submission; under limited circumstances we will grant untimely-filed requests for the extension of time limits. Review *Extension of Time Limits; Final Rule,* 78 FR 57790 (September 20, 2013), available at *http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm,* prior to submitting factual information in this segment.

Certification Requirements

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information.[45] Parties are hereby reminded that revised certification requirements are in effect for company/government officials, as well as their representatives. Investigations initiated on the basis of Petitions filed on or after August 16, 2013, and other segments of any AD or CVD proceedings initiated on or after August 16, 2013, should use the formats for the revised certifications provided at the end of the *Final Rule.*[46] The Department intends to reject factual submissions if the submitting party does not comply with applicable revised certification requirements.

Notification to Interested Parties

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305. On January 22, 2008, the Department published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures,* 73 FR 3634 (January

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[40] *See Dates of Application of Amendments to the Antidumping and Countervailing Duty Laws Made by the Trade Preferences Extension Act of 2015,* 80 FR 46793 (August 6, 2015) (*Applicability Notice*).

[41] *Id.,* at 46794–95. The 2015 amendments may be found at *https://www.congress.gov/bill/114th-congress/house-bill/1295/text/pl.*

[42] *See* Volume I of the Petitions, at Exhibit I–6, Exhibit I–7, and Exhibit I–8.

[43] *See* section 733(a) of the Act.

[44] *Id.*

[45] *See* section 782(b) of the Act.

[46] *See Certification of Factual Information to Import Administration during Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (*Final Rule*); *see also* frequently asked questions regarding the *Final Rule,* available at *http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

22, 2008). Parties wishing to participate in these investigations should ensure that they meet the requirements of these procedures (*e.g.*, the filing of letters of appearance as discussed in 19 CFR 351.103(d)).

This notice is issued and published pursuant to section 777(i) of the Act.

Dated: July 20, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Investigations

The scope of these investigations covers finished carbon steel flanges. Finished carbon steel flanges differ from unfinished carbon steel flanges (also known as carbon steel flange forgings) in that they have undergone further processing after forging, including, but not limited to, beveling, bore threading, center or step boring, face machining, taper boring, machining ends or surfaces, drilling bolt holes, and/or de-burring or shot blasting. Any one of these post-forging processes suffices to render the forging into a finished carbon steel flange for purposes of these investigations. However, mere heat treatment of a carbon steel flange forging (without any other further processing after forging) does not render the forging into a finished carbon steel flange for purposes of these investigations.

While these finished carbon steel flanges are generally manufactured to specification ASME 816.5 or ASME 816.47 series A or series 8, the scope is not limited to flanges produced under those specifications. All types of finished carbon steel flanges are included in the scope regardless of pipe size (which may or may not be expressed in inches of nominal pipe size), pressure class (usually, but not necessarily, expressed in pounds of pressure, *e.g.*, 150, 300, 400, 600, 900, 1500, 2500, etc.), type of face (*e.g.*, flat face, full face, raised face, etc.), configuration (*e.g.*, weld neck, slip on, socket weld, lap joint, threaded, etc.), wall thickness (usually, but not necessarily, expressed in inches), normalization, or whether or not heat treated. These carbon steel flanges either meet or exceed the requirements of the ASTM A105, ASTM A694, ASTM A181, ASTM A350 and ASTM A707 standards (or comparable foreign specifications). The scope includes any flanges produced to the above-referenced ASTM standards as currently stated or as may be amended. The term "carbon steel" under this scope is steel in which:

(a) Iron predominates, by weight, over each of the other contained elements:

(b) The carbon content is 2 percent or less, by weight; and

(c) none of the elements listed below exceeds the quantity, by weight, as indicated:

(i) 0.87 percent of aluminum;
(ii) 0.0105 percent of boron;
(iii) 10.10 percent of chromium;
(iv) 1.55 percent of columbium;
(v) 3.10 percent of copper;
(vi) 0.38 percent of lead;
(vii) 3.04 percent of manganese;
(viii) 2.05 percent of molybdenum;
(ix) 20.15 percent of nickel;
(x) 1.55 percent of niobium;
(xi) 0.20 percent of nitrogen;
(xii) 0.21 percent of phosphorus;
(xiii) 3.10 percent of silicon;
(xiv) 0.21 percent of sulfur;
(xv) 1.05 percent of titanium;
(xvi) 4.06 percent of tungsten;
(xvii) 0.53 percent of vanadium; or
(xviii) 0.015 percent of zirconium.

Finished carbon steel flanges are currently classified under subheadings 7307.91.5010 and 7307.91.5050 of the Harmonized Tariff Schedule of the United States (HTSUS). They may also be entered under HTSUS subheadings 7307.91.5030 and 7307.91.5070. The HTSUS subheadings are provided for convenience and customs purposes; the written description of the scope is dispositive.

[FR Doc. 2016–17931 Filed 7–27–16; 8:45 a.m.]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–044]

Antidumping Duty Investigation of 1,1,1,2 Tetrafluoroethane (R–134a) From the People's Republic of China: Postponement of Preliminary Determination of Antidumping Duty Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* July 28, 2016.

FOR FURTHER INFORMATION CONTACT: Keith Haynes, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–5139.

SUPPLEMENTARY INFORMATION:

Background

On March 23, 2016, the Department of Commerce ("Department") initiated an antidumping duty investigation on 1,1,1,2 Tetrafluoroethane ("R–134a") from the People's Republic of China ("PRC").[1] The notice of initiation stated that, in accordance with section 733(b)(l)(A) of the Tariff Act of 1930, as amended ("the Act"), and 19 CFR 351.205(b)(1), we would issue our preliminary determination no later than 140 days after the date of initiation, unless postponed. Currently, the preliminary determination in this investigation is due no later than August 10, 2016. On July 13, 2016, the American HFC Coalition and its individual members,[2] as well as District Lodge 154 of the International Association of Machinists and Aerospace Workers (collectively, "Petitioners"), requested that the Department postpone its preliminary determination for the above mentioned investigation.

Postponement of Preliminary Determination

Section 733(b)(1) of the Act requires the Department to issue the preliminary determination in an antidumping duty investigation within 140 days after the date on which the Department initiated the investigation. However, if the petitioner makes a timely request for a postponement, section 733(c)(1)(A) of the Act allows the Department to postpone the preliminary determination until no later than 190 days after the date on which the Department initiated the investigation. On July 13, 2016, Petitioners submitted a timely request pursuant to section 733(c)(1)(A) of the Act and 19 CFR 351.205(e).[3] The Department finds that there are no compelling reasons to deny Petitioners' request. The Department is postponing the deadline for the preliminary determination to no later than 190 days after the day on which the investigation was initiated, in accordance with section 733(c)(1)(A) of the Act. Accordingly, the Department will issue the preliminary determination in this investigation no later than September 29, 2016. In accordance with section 735(a)(1) of the Act and 19 CFR 351.210(b)(1), the deadline for the final determination of this investigation will continue to be 75 days after the date of the preliminary determination, unless postponed at a later date.

This notice is issued and published pursuant to section 733(c)(2) of the Act and 19 CFR 351.205(f)(1).

Dated: July 21, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2016–17805 Filed 7–27–16; 8:45 am]

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[1] *See Antidumping Duty Investigation of 1,1,1,2 Tetrafluoroethane ("R–134a") from the People's Republic of China: Initiation of Antidumping Duty Investigation,* 81 FR 18830 (April 1, 2016).

[2] The individual members of the American HFC Coalition are: Amtrol Inc., Arkema Inc., The Chemours Company FC LLC, Honeywell International Inc., Hudson Technologies, Mexichem Fluor Inc., and Worthington Industries, Inc.

[3] *See* letter from Petitioners, "1,1,1,2 Tetrafluoroethane (R–134a) from the People's Republic of China: Petitioners' Request for Extension of the Antidumping Investigation Preliminary Determination," dated July 13, 2016.

DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–872]

Finished Carbon Steel Flanges From India: Initiation of Countervailing Duty Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* July 20, 2016.

FOR FURTHER INFORMATION CONTACT: Yasmin Bordas at (202) 482–3813, or Davina Friedmann at (202) 482–0698, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

The Petition

On September 30, 2015, the Department of Commerce (Department) received a countervailing duty (CVD) petition concerning imports of finished carbon steel flanges (steel flanges) from India, filed in proper form on behalf of Weldbend Corporation & Boltex Mfg. Co., L.P. (collectively, Petitioners). The CVD petition was accompanied by antidumping duty (AD) petitions concerning imports of steel flanges from India, Italy, and Spain.[1] Petitioners are domestic producers of steel flanges.[2]

On July 6, 2016, the Department requested information and clarification for certain areas of the Petition.[3] Petitioners filed responses to these requests on July 8, 2016, and July 11, 2016.[4]

In accordance with section 702(b)(1) of the Tariff Act of 1930, as amended (the Act), Petitioners allege that the Government of India (GOI) is providing countervailable subsidies (within the meaning of sections 701 and 771(5) of the Act) to imports of steel flanges from India, and that such imports are materially injuring, or threatening material injury to, an industry in the United States. Also, consistent with section 702(b)(1) of the Act, for those alleged programs in India on which we have initiated a CVD investigation, the Petition is accompanied by information reasonably available to Petitioners supporting their allegations.

The Department finds that Petitioners filed the Petition on behalf of the domestic industry because Petitioners are interested parties as defined in section 771(9)(C) of the Act. The Department also finds that Petitioners demonstrated sufficient industry support with respect to the initiation of the CVD investigation that Petitioners are requesting.[5]

Period of Investigation

The period of investigation is January 1, 2015, through December 31, 2015.[6]

Scope of the Investigation

The product covered by this investigation is steel flanges from India. For a full description of the scope of this investigation, *see* the "Scope of the Investigation" in Appendix I of this notice.

Comments on Scope of the Investigation

During our review of the Petitions, the Department issued questions to, and received responses from, Petitioners pertaining to the proposed scope to ensure that the scope language in the Petitions would be an accurate reflection of the products for which the domestic industry is seeking relief.[7]

As discussed in the preamble to the Department's regulations, we are setting aside a period for interested parties to raise issues regarding product coverage (scope). The Department will consider all comments received from parties and, if necessary, will consult with parties prior to the issuance of the preliminary determinations. If scope comments include factual information (*see* 19 CFR 351.102(b)(21)), all such factual information should be limited to public information. In order to facilitate preparation of its questionnaires, the Department requests all interested parties to submit such comments by 5:00 p.m. Eastern Daylight Time (EDT) on August 9, 2016, which is 20 calendar days from the signature date of this notice. Any rebuttal comments, which may include factual information, must be filed by 5:00 p.m. EDT on August 19, 2016, which is 10 calendar days after the initial comments.

The Department requests that any factual information the parties consider relevant to the scope of the investigations be submitted during this time period. However, if a party subsequently finds that additional factual information pertaining to the scope of the investigations may be relevant, the party may contact the Department and request permission to submit the additional information. All such comments must be filed on the records of each of the concurrent AD and CVD investigations.

Filing Requirements

All submissions to the Department must be filed electronically using Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS).[8] An electronically-filed document must be received successfully in its entirety by the time and date it is due. Documents excepted from the electronic submission requirements must be filed manually (*i.e.*, in paper form) with Enforcement and Compliance's APO/Dockets Unit, Room 18022, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, and stamped with the date and time of receipt by the applicable deadlines.

Consultations

Pursuant to section 702(b)(4)(A)(i) of the Act, the Department notified representatives of the GOI of the receipt of the Petition. Also, in accordance with section 702(b)(4)(A)(ii) of the Act, the Department provided representatives of the GOI the opportunity for consultations with respect to the CVD petition. On July 19, 2016, consultations were held with the GOI. All invitation letters and memoranda regarding these consultations are on file electronically *via* ACCESS.

Determination of Industry Support for the Petition

Section 702(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 702(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) At least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 702(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, the Department shall: (i) Poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the "industry."

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[1] *See* "Petition for the Imposition of Antidumping and Countervailing Duties: Finished Carbon Steel Flanges from India," dated June 30, 2016 (Petition).

[2] *See* Volume I of the Petition, at 2.

[3] *See* letter from the Department, "Petitions for the Imposition of Antidumping Duties on Imports of Finished Carbon Steel Flanges from India, Italy, and Spain and Countervailing Duties on Imports from India: Supplemental Questions," dated July 6, 2016 (General Issues Questionnaire); letter from the Department, "Petition for the Imposition of Countervailing Duties on Imports of Carbon Steel Flanges from India: Supplemental Questions," July 6, 2016 (CVD Deficiency Questionnaire).

[4] *See* letters from Petitioners, "Finished Carbon Steel Flanges from India: Response to Supplemental Questions," dated July 8, 2016, and July 13, 2016, covering volume I (General Issues Supplement); letters from Petitioners, "Finished Carbon Steel Flanges from India: Response to CVD Supplement" dated July 8, 2016, and July 11, 2016.

[5] *See* the "Determination of Industry Support for the Petition" section below.

[6] *See* 19 CFR 351.204(b)(2).

[7] *See* General Issues Supplemental Questionnaire and Second General Issues Supplemental Questionnaire; *see also* General Issues Supplement and Second General Issues Supplement.

[8] *See* 19 CFR 351.303 (for general filing requirements); *Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011), for details of the Department's electronic filing requirements, which went into effect on August 5, 2011. Information on help using ACCESS can be found at *https://access.trade.gov/help.aspx* and a handbook can be found at *https://access.trade.gov/help/Handbook%20on%20Electronic%20Filling%20Procedures.pdf.*

Section 771(4)(A) of the Act defines the "industry" as the producers as a whole of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs the Department to look to producers and workers who produce the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether "the domestic industry" has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both the Department and the ITC must apply the same statutory definition regarding the domestic like product,[9] they do so for different purposes and pursuant to a separate and distinct authority. In addition, the Department's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law.[10]

Section 771(10) of the Act defines the domestic like product as "a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title." Thus, the reference point from which the domestic like product analysis begins is "the article subject to an investigation" (*i.e.*, the class or kind of merchandise to be investigated, which normally will be the scope as defined in the Petition).

With regard to the domestic like product, Petitioners do not offer a definition of the domestic like product distinct from the scope of the investigation. Based on our analysis of the information submitted on the record, we have determined that steel flanges constitute a single domestic like product and we have analyzed industry support in terms of that domestic like product.[11]

In determining whether Petitioners have standing under section 702(c)(4)(A) of the Act, we considered the industry support data contained in the Petition with reference to the domestic like product as defined in the "Scope of the Investigation," in Appendix I of this notice. Petitioners provided their production of the domestic like product in 2015,[12] as well as an estimate of the total 2015 production of the domestic like product for the entire domestic industry.[13] To establish industry support, Petitioners compared their own production to the estimated total production of the domestic like product for the entire domestic industry.[14]

Our review of the data provided in the Petition and other information readily available to the Department indicates that Petitioners have established industry support.[15] First, the Petition established support from domestic producers (or workers) accounting for more than 50 percent of the total production of the domestic like product and, as such, the Department is not required to take further action in order to evaluate industry support (*e.g.*, polling).[16] Second, the domestic producers (or workers) have met the statutory criteria for industry support under section 702(c)(4)(A)(i) of the Act because the domestic producers (or workers) who support the Petition account for at least 25 percent of the total production of the domestic like product.[17] Finally, the domestic producers (or workers) have met the statutory criteria for industry support under section 702(c)(4)(A)(ii) of the Act because the domestic producers (or workers) who support the Petition account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petition.[18] Accordingly, the Department determines that the Petition was filed on behalf of the domestic industry within the meaning of section 702(b)(1) of the Act.

The Department finds that Petitioners filed the Petition on behalf of the domestic industry because they are interested parties as defined in section 771(9)(C) of the Act and they have demonstrated sufficient industry support with respect to the CVD investigation that they are requesting the Department initiate.[19]

Injury Test

Because India is a "Subsidies Agreement Country" within the meaning of section 701(b) of the Act, section 701(a)(2) of the Act applies to this investigation. Accordingly, the ITC must determine whether imports of the subject merchandise from India materially injure, or threaten material injury to, a U.S. industry.

Allegations and Evidence of Material Injury and Causation

Petitioners allege that imports of the subject merchandise are benefitting from countervailable subsidies and that such imports are causing, or threaten to cause, material injury to the U.S. industry producing the domestic like product. In addition, Petitioners allege that subject imports exceed the negligibility threshold provided for under section 771(24)(A) of the Act.[20]

In CVD petitions, section 771(24)(B) of the Act provides that imports of subject merchandise from developing and least developed countries must exceed the negligibility threshold of four percent. The import data provided by Petitioners demonstrate that subject imports from India, which has been designated as a least developed country,[21] exceed the negligibility threshold provided for under section 771(24)(B) of the Act.[22]

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[9] *See* section 771(10) of the Act.

[10] *See USEC, Inc.* v. *United States,* 132 F. Supp. 2d 1, 8 (CIT 2001) (citing *Algoma Steel Corp., Ltd.* v. *United States,* 688 F. Supp. 639, 644 (CIT 1988), *aff'd* 865 F.2d 240 (Fed. Cir. 1989)).

[11] For a discussion of the domestic like product analysis in this case, *see* Countervailing Duty Investigation Initiation Checklist: Finished Carbon Steel Flanges from India (India CVD Initiation Checklist), at Attachment II, Analysis of Industry Support for the Antidumping and Countervailing Duty Petitions Covering Finished Carbon Steel Flanges from India, Italy, and Spain (Attachment II). This checklist is dated concurrently with this notice and on file electronically via ACCESS. Access to documents filed via ACCESS is also available in the Central Records Unit, Room B8024 of the main Department of Commerce building.

[12] *See* Volume I of the Petition, at Exhibits I–15–A and I–15–B.

[13] *See* Volume I of the Petition, at Exhibits I–15–A and I–15–B.

[14] *Id.*

[15] *See* India CVD Initiation Checklist, at Attachment II.

[16] *See* section 702(c)(4)(D) of the Act; *see also* India CVD Initiation Checklist, at Attachment II.

[17] *See* India CVD Initiation Checklist, at Attachment II.

[18] *Id.*

[19] *Id.*

[20] *See* Volume I of the Petition, at 18–19; *see also* General Issues Supplement, at 6 and Exhibit 3.

[21] *See* section 771(36)(B) of the Act.

[22] *See* Volume I of the Petition, at 18–19; *see also* General Issues Supplement, at 6 and Exhibit 3.

Petitioners contend that the industry's injured condition is illustrated by reduced market share, underselling and price suppression or depression, lost sales and revenues, declines in production, capacity utilization, and U.S. shipments, negative impact on employment variables, and decline in financial performance.[23] We have assessed the allegations and supporting evidence regarding material injury, threat of material injury, and causation, and we have determined that these allegations are properly supported by adequate evidence and meet the statutory requirements for initiation.[24]

Initiation of Countervailing Duty Investigation

Section 702(b)(1) of the Act requires the Department to initiate a CVD investigation whenever an interested party files a CVD petition on behalf of an industry that: (1) Alleges the elements necessary for an imposition of a duty under section 701(a) of the Act; and (2) is accompanied by information reasonably available to Petitioners supporting the allegations.

Petitioners allege that producers/exporters of steel flanges in India benefit from countervailable subsidies bestowed by the GOI. The Department examined the Petition and finds that it complies with the requirements of section 702(b)(1) of the Act. Therefore, in accordance with section 702(b)(1) of the Act, we are initiating a CVD investigation to determine whether manufacturers, producers, or exporters of steel flanges from India receive countervailable subsidies from the GOI.

On June 29, 2015, the President of the United States signed into law the Trade Preferences Extension Act of 2015, which made numerous amendments to the AD and CVD law.[25] The 2015 law does not specify dates of application for those amendments. On August 6, 2015, the Department published an interpretative rule, in which it announced the applicability dates for each amendment to the Act, except for amendments contained in section 771(7) of the Act, which relate to determinations of material injury by the ITC.[26] The amendments to sections 776 and 782 of the Act are applicable to all determinations made on or after August 6, 2015, and, therefore, apply to this CVD investigation.[27]

Based on our review of the petition, we find that there is sufficient information to initiate a CVD investigation on 15 of the 99 alleged programs in India. For a full discussion of the basis for our decision to initiate or not initiate on each program, *see* the India CVD Initiation Checklist. A public version of the initiation checklist for this investigation is available on ACCESS.

In accordance with section 703(b)(1) of the Act and 19 CFR 351.205(b)(1), unless postponed, we will make our preliminary determination no later than 65 days after the date of this initiation.

Respondent Selection

Petitioners named 34 companies as producers/exporters of steel flanges in India.[28] Following standard practice in CVD investigations, the Department will, where appropriate, select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports of steel flanges during the period of investigation. We intend to release CBP data under Administrative Protective Order (APO) to all parties with access to information protected by APO within five business days of publication of this **Federal Register** notice. The Department invites comments regarding respondent selection within seven business days of publication of this **Federal Register** notice.

Comments must be filed electronically using ACCESS. An electronically-filed document must be received successfully in its entirety by ACCESS, by 5 p.m. EDT by the date noted above. We intend to make our decision regarding respondent selection within 20 days of publication of this notice. Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305(b). Instructions for filing such applications may be found on the Department's Web site at *http://enforcement.trade.gov/apo.*

Distribution of Copies of the Petition

In accordance with section 702(b)(4)(A)(i) of the Act and 19 CFR 351.202(f), a copy of the public version of the Petition has been provided to the GOI *via* ACCESS. To the extent practicable, we will attempt to provide a copy of the public version of the Petition to each known exporter (as named in the Petition), consistent with 19 CFR 351.203(c)(2).

ITC Notification

We will notify the ITC of our initiation, as required by section 702(d) of the Act.

Preliminary Determinations by the ITC

The ITC will preliminarily determine, within 45 days after the date on which the Petition was filed, whether there is a reasonable indication that imports of steel flanges from India are materially injuring, or threatening material injury to, a U.S. industry.[29] A negative ITC determination will result in the investigation being terminated;[30] otherwise, this investigation will proceed according to statutory and regulatory time limits.

Submission of Factual Information

Factual information is defined in 19 CFR 351.102(b)(21) as: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by the Department; and (v) evidence other than factual information described in (i)–(iv). The regulation requires any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct. Time limits for the submission of factual information are addressed in 19 CFR 351.301, which provides specific time limits based on the type of factual information being submitted. Parties should review the regulations prior to submitting factual information in this investigation.

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[23] *See* Volume I of the Petition, at 12–16, 18–34 and Exhibits I–2, I–9 and I–11 through I–14; *see also* General Issues Supplement, at 6 and Exhibit 3.

[24] *See* India CVD Initiation Checklist, at Attachment III, Analysis of Allegations and Evidence of Material Injury and Causation for the Antidumping and Countervailing Duty Petitions Covering Finished Carbon Steel Flanges from India, Italy, and Spain.

[25] *See* Trade Preferences Extension Act of 2015, Public Law 114–27, 129 Stat. 362 (2015).

[26] *See Dates of Application of Amendments to the Antidumping and Countervailing Duty Laws Made by the Trade Preferences Extension Act of 2015,* 80 FR 46793 (August 6, 2015) (*Applicability Notice*). The 2015 amendments may be found at *https://www.congress.gov/bill/114th-congress/house-bill/1295/text/pl.*

[27] *See Dates of Application of Amendments to the Antidumping and Countervailing Duty Laws Made by the Trade Preferences Extension Act of 2015,* 80 FR 46793 (August 6, 2015) (*Applicability Notice*), at 46794–95. The 2015 amendments may be found at *https://www.congress.gov/bill/114th-congress/house-bill/1295/text/pl.*

[28] *See* Volume I of the Petition, at Exhibit I–6.

[29] *See* section 703(a)(2) of the Act.

[30] *See* section 703(a)(1) of the Act.

Extension of Time Limits Regulation

Parties may request an extension of time limits before the expiration of a time limit established under 19 CFR 351.301, or as otherwise specified by the Secretary. In general, an extension request will be considered untimely if it is filed after the expiration of the time limit established under 19 CFR 351.301 expires. For submissions that are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. on the due date. Under certain circumstances, we may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, we will inform parties in the letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. An extension request must be made in a separate, stand-alone submission; under limited circumstances we will grant untimely-filed requests for the extension of time limits. Review *Extension of Time Limits; Final Rule,* 78 FR 57790 (September 20, 2013), available at *http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm,* prior to submitting factual information in this investigation.

Certification Requirements

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information.[31] Parties are hereby reminded that revised certification requirements are in effect for company/government officials, as well as their representatives. Investigations initiated on the basis of petitions filed on or after August 16, 2013, and other segments of any AD or CVD proceedings initiated on or after August 16, 2013, should use the formats for the revised certifications provided at the end of the *Final Rule.*[32] The Department intends to reject factual submissions if the submitting party does not comply with the applicable revised certification requirements.

Notification to Interested Parties

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305. On January 22, 2008, the Department published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures,* 73 FR 3634 (January 22, 2008). Parties wishing to participate in this investigation should ensure that they meet the requirements of these procedures (*e.g.,* the filing of letters of appearance as discussed at 19 CFR 351.103(d)).

This notice is issued and published pursuant to sections 702 and 777(i) of the Act.

Dated: July 20, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Investigation

The scope of this investigation covers finished carbon steel flanges. Finished carbon steel flanges differ from unfinished carbon steel flanges (also known as carbon steel flange forgings) in that they have undergone further processing after forging, including, but not limited to, beveling, bore threading, center or step boring, face machining, taper boring, machining ends or surfaces, drilling bolt holes, and/or de-burring or shot blasting. Any one of these post-forging processes suffices to render the forging into a finished carbon steel flange for purposes of this investigation. However, mere heat treatment of a carbon steel flange forging (without any other further processing after forging) does not render the forging into a finished carbon steel flange for purposes of this investigation.

While these finished carbon steel flanges are generally manufactured to specification ASME 816.5 or ASME 816.47 series A or series 8, the scope is not limited to flanges produced under those specifications. All types of finished carbon steel flanges are included in the scope regardless of pipe size (which may or may not be expressed in inches of nominal pipe size), pressure class (usually, but not necessarily, expressed in pounds of pressure, *e.g.,* 150, 300, 400, 600, 900, 1500, 2500, etc.), type of face (*e.g.,* flat face, full face, raised face, etc.), configuration (*e.g.,* weld neck, slip on, socket weld, lap joint, threaded, etc.), wall thickness (usually, but not necessarily, expressed in inches), normalization, or whether or not heat treated. These carbon steel flanges either meet or exceed the requirements of the ASTM A105, ASTM A694, ASTM A181, ASTM A350 and ASTM A707 standards (or comparable foreign specifications). The scope includes any flanges produced to the above-referenced ASTM standards as currently stated or as may be amended. The term "carbon steel" under this scope is steel in which:

(a) Iron predominates, by weight, over each of the other contained elements:

(b) The carbon content is 2 percent or less, by weight; and

(c) none of the elements listed below exceeds the quantity, by weight, as indicated:

(i) 0.87 percent of aluminum;
(ii) 0.0105 percent of boron;
(iii) 10.10 percent of chromium;
(iv) 1.55 percent of columbium;
(v) 3.10 percent of copper;
(vi) 0.38 percent of lead;
(vii) 3.04 percent of manganese;
(viii) 2.05 percent of molybdenum;
(ix) 20.15 percent of nickel;
(x) 1.55 percent of niobium;
(xi) 0.20 percent of nitrogen;
(xii) 0.21 percent of phosphorus;
(xiii) 3.10 percent of silicon;
(xiv) 0.21 percent of sulfur;
(xv) 1.05 percent of titanium;
(xvi) 4.06 percent of tungsten;
(xvii) 0.53 percent of vanadium; or
(xviii) 0.015 percent of zirconium.

Finished carbon steel flanges are currently classified under subheadings 7307.91.5010 and 7307.91.5050 of the Harmonized Tariff Schedule of the United States (HTSUS). They may also be entered under HTSUS subheadings 7307.91.5030 and 7307.91.5070. The HTSUS subheadings are provided for convenience and customs purposes; the written description of the scope is dispositive.

[FR Doc. 2016–17929 Filed 7–27–16; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–889]

Dioctyl Terephthalate From the Republic of Korea: Initiation of Less-Than-Fair-Value Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* July 20, 2016.

FOR FURTHER INFORMATION CONTACT: Shanah Lee or Eve Wang, at (202) 482–6386 or (202) 482–6231, AD/CVD Operations, Enforcement and Compliance, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

The Petition

On June 30, 2016, the Department of Commerce ("the Department") received an antidumping duty ("AD") petition concerning imports of dioctyl terephthalate ("DOTP") from the Republic of Korea ("Korea"), filed in proper form on behalf of Eastman Chemical Company ("Petitioner").[1] Petitioner is a domestic producer of DOTP.[2]

On July 5, 2016, the Department requested additional information and clarification of certain areas of the

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[31] *See* section 782(b) of the Act.

[32] *See Certification of Factual Information To Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) ("*Final Rule*"); *see also* frequently asked questions regarding the *Final Rule,* available at *http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

[1] *See* the "Petition for the Imposition of Antidumping Duties on Imports of Dioctyl Terephthalate from the Republic of Korea," dated June 30, 2016 ("Petition").

[2] *See* Petition, at 3.

Petition.[3] Petitioner filed its response on July 7, 2016.[4]

In accordance with section 732(b) of the Tariff Act of 1930, as amended ("the Act"), Petitioner alleges that imports of DOTP from Korea are being, or are likely to be, sold in the United States at less-than-fair value within the meaning of section 731 of the Act, and that such imports are materially injuring, or threatening material injury to, an industry in the United States. Also, consistent with section 732(b)(1) of the Act, the Petition is accompanied by information reasonably available to Petitioner supporting its allegations.

The Department finds that Petitioner filed this Petition on behalf of the domestic industry because Petitioner is an interested party as defined in section 771(9)(C) of the Act. The Department also finds that Petitioner demonstrated sufficient industry support with respect to the initiation of the AD investigation that Petitioner is requesting.[5]

Period of Investigation

Because the Petition was filed on June 30, 2016, the period of investigation ("POI") is, pursuant to 19 CFR 351.204(b)(1), April 1, 2015, through March 31, 2016.

Scope of the Investigation

The merchandise covered by this investigation is DOTP from Korea. For a full description of the scope of this investigation, *see* the "Scope of the Investigation," in Appendix I of this notice.

Comments on Scope of the Investigation

During our review of the Petition, the Department issued questions to, and received responses from, Petitioner pertaining to the proposed scope to ensure that the scope language in the Petition would be an accurate reflection of the products for which the domestic industry is seeking relief.[6]

As discussed in the preamble to the Department's regulations,[7] we are setting aside a period for interested parties to raise issues regarding product coverage (scope). The Department will consider all comments received from parties and, if necessary, will consult with parties prior to the issuance of the preliminary determination. If scope comments include factual information (*see* 19 CFR 351.102(b)(21)), all such factual information should be limited to public information. In order to facilitate preparation of its questionnaires, the Department requests all interested parties to submit such comments by 5:00 p.m. Eastern Daylight Time ("EDT") on Tuesday, August 9, 2016, which is 20 calendar days from the signature date of this notice. Any rebuttal comments, which may include factual information, must be filed by 5:00 p.m. EDT on Friday, August 19, 2016, which is ten calendar days after the initial comments deadline.

The Department requests that any factual information the parties consider relevant to the scope of the investigation be submitted during this time period. However, if a party subsequently finds that additional factual information pertaining to the scope of the investigation may be relevant, the party may contact the Department and request permission to submit the additional information.

Filing Requirements

All submissions to the Department must be filed electronically using Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System ("ACCESS").[8] An electronically filed document must be received successfully in its entirety by the time and date when it is due. Documents excepted from the electronic submission requirements must be filed manually (*i.e.*, in paper form) with Enforcement and Compliance's APO/Dockets Unit, Room 18022, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, and stamped with the date and time of receipt by the applicable deadlines.

Comments on Product Characteristics for AD Questionnaires

The Department requests comments from interested parties regarding the appropriate physical characteristics of DOTP to be reported in response to the Department's AD questionnaires. This information will be used to identify the key physical characteristics of the subject merchandise in order to report the relevant costs of production accurately as well as to develop appropriate product-comparison criteria.

Interested parties may provide any information or comments that they feel are relevant to the development of an accurate list of physical characteristics. Specifically, they may provide comments as to which characteristics are appropriate to use as: (1) General product characteristics and (2) product-comparison criteria. We note that it is not always appropriate to use all product characteristics as product-comparison criteria. We base product-comparison criteria on meaningful commercial differences among products. In other words, although there may be some physical product characteristics utilized by manufacturers to describe DOTP, it may be that only a select few product characteristics take into account commercially meaningful physical characteristics. In addition, interested parties may comment on the order in which the physical characteristics should be used in matching products. Generally, the Department attempts to list the most important physical characteristics first and the least important characteristics last.

In order to consider the suggestions of interested parties in developing and issuing the AD questionnaires, all comments must be filed by 5:00 p.m. EDT on August 9, 2016, which is 20 calendar days from the signature date of this notice. Any rebuttal comments must be filed by 5:00 p.m. EDT on August 19, 2016. All comments and submissions to the Department must be filed electronically using ACCESS, as explained above, on the record of this less-than-fair-value investigation.

Determination of Industry Support for the Petition

Section 732(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 732(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) At least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 732(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, the Department shall: (i) Poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the "industry."

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[3] *See* Letter from the Department to Petitioner entitled "Petition for the Imposition of Antidumping Duties on Imports of Dioctyl Terephthalate from the Republic of Korea: Supplemental Questions" dated July 5, 2016.

[4] *See* Letter from Petitioner entitled "Petitioner's Response to the Department's January [sic] 5, 2016 Supplemental Questions Regarding the Petition," dated July 7, 2016 ("Petition Supplement").

[5] *See* the "Determination of Industry Support for the Petition" section below.

[6] *See* Petition Supplement, at 1–2.

[7] *See Antidumping Duties; Countervailing Duties,* 62 FR 27296, 27323 (May 19, 1997).

[8] *See* 19 CFR 351.303 (for general filing requirements); *see also Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011); *see also Enforcement and Compliance; Change of Electronic Filing System Name,* 79 FR 69046 (November 20, 2014) for details of the Department's electronic filing requirements, which went into effect on August 5, 2011. Information on help using ACCESS can be found at *https://access.trade.gov/help.aspx* and a handbook can be found at *https://access.trade.gov/help/Handbook%20on%20Electronic%20Filling%20Procedures.pdf.*

Section 771(4)(A) of the Act defines the "industry" as the producers as a whole of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs the Department to look to producers and workers who produce the domestic like product. The International Trade Commission ("ITC"), which is responsible for determining whether "the domestic industry" has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both the Department and the ITC must apply the same statutory definition regarding the domestic like product,[9] they do so for different purposes and pursuant to a separate and distinct authority. In addition, the Department's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law.[10]

Section 771(10) of the Act defines the domestic like product as "a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title." Thus, the reference point from which the domestic like product analysis begins is "the article subject to an investigation" (*i.e.,* the class or kind of merchandise to be investigated, which normally will be the scope as defined in the Petition).

With regard to the domestic like product, Petitioner does not offer a definition of the domestic like product distinct from the scope of the investigation. Based on our analysis of the information submitted on the record, we have determined that DOTP, as defined in the scope, constitutes a single domestic like product and we have analyzed industry support in terms of that domestic like product.[11]

In determining whether Petitioner has standing under section 732(c)(4)(A) of the Act, we considered the industry support data contained in the Petition with reference to the domestic like product as defined in the "Scope of the Investigation," in Appendix I of this notice. To establish industry support, Petitioner provided its 2015 production of the domestic like product.[12] Petitioner states that it is the only known producer of DOTP in the United States; therefore, the Petition is supported by 100 percent of the U.S. industry.[13]

Our review of the data provided in the Petition and other information readily available to the Department indicates that Petitioner has established U.S. industry support.[14] First, the Petition established support from U.S. domestic producers (or workers) accounting for more than 50 percent of the total production of the domestic like product and, as such, the Department is not required to take further action in order to evaluate industry support (*e.g.,* polling).[15] Second, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(i) of the Act because the domestic producers (or workers) who support the Petition account for at least 25 percent of the total production of the domestic like product.[16] Finally, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(ii) of the Act because the domestic producers (or workers) who support the Petition account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petition.[17] Accordingly, the Department determines that the Petition was filed on behalf of the domestic industry within the meaning of section 732(b)(1) of the Act.

The Department finds that Petitioner filed the Petition on behalf of the domestic industry because it is an interested party as defined in section 771(9)(C) of the Act and it has demonstrated sufficient industry support with respect to the AD investigation that it is requesting the Department initiate.[18]

Allegations and Evidence of Material Injury and Causation

Petitioner alleges that the U.S. industry producing the domestic like product is being materially injured, or is threatened with material injury, by reason of the imports of the subject merchandise sold at less than normal value ("NV"). In addition, Petitioner alleges that subject imports exceed the negligibility threshold provided for under section 771(24)(A) of the Act.[19] Petitioner contends that the industry's injured condition is illustrated by the impact on the domestic industry's market share, underselling and price suppression or depression, lost sales and revenues, decline in wages and employment, and decline in profitability.[20] We have assessed the allegations and supporting evidence regarding material injury, threat of material injury, and causation, and we have determined that these allegations are properly supported by adequate evidence, and meet the statutory requirements for initiation.[21]

Allegation of Sales at Less-Than-Fair Value

The following is a description of the allegation of sales at less-than-fair value upon which the Department based its decision to initiate the investigation of imports of DOTP from Korea. The sources of data for the deductions and adjustments relating to U.S. price and NV are discussed in greater detail in the AD initiation checklist.

Export Price

Petitioner based export prices on a Korean producer's price offerings to its customers in the United States for DOTP produced in, and exported from, Korea during the POI.[22] Because the quoted prices included delivery to the customer, Petitioner made a deduction from U.S. price for producer-to-customer freight.[23]

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[9] *See* section 771(10) of the Act.

[10] *See USEC, Inc.* v. *United States,* 132 F. Supp. 2d 1, 8 (CIT 2001) (citing *Algoma Steel Corp., Ltd.* v. *United States,* 688 F. Supp. 639, 644 (CIT 1988), *aff'd* 865 F.2d 240 (Fed. Cir. 1989)).

[11] For a discussion of the domestic like product analysis in this case, *see* "AD Investigation Initiation Checklist: Dioctyl Terephthalate from the Republic of Korea ("AD Initiation Checklist"), at Attachment II, Determination of Industry Support for the Petition. This checklist is dated concurrently with this notice and on file electronically via ACCESS. Access to documents filed via ACCESS is also available in the Central Records Unit, Room B8024 of the main Department of Commerce building.

[12] *See* Petition, at 3 and Exhibit INJ–4.

[13] *Id.,* at 3.

[14] *See* AD Initiation Checklist, at Attachment II.

[15] *See* section 732(c)(4)(D) of the Act; *see also* AD Initiation Checklist, at Attachment II.

[16] *See* AD Initiation Checklist, at Attachment II.

[17] *Id.*

[18] *Id.*

[19] *See* Petition, at 13–14; *see also* Petition Supplement, at 2 and Exhibit Supp–1.

[20] *See* Petition, at 2, 11–35 and Exhibits GEN–3 through GEN–6, GEN–10 and INJ–1 through INJ–7; *see also* Petition Supplement, at 2–3 and Exhibit Supp–1.

[21] *See* AD Initiation Checklist, at Attachment III, Analysis of Allegations and Evidence of Material Injury and Causation for the Antidumping Duty Petition Covering Dioctyl Terephthalate from the Republic of Korea.

[22] *See* AD Initiation Checklist; *see also* Petition, at 38–39 and Exhibits AD–1, AD–5, and AD–6; *see also* Petition Supplement, at Exhibit Supp–3.

[23] *See* AD Initiation Checklist.

Normal Value

Petitioner provided home market price information from an industry report for DOTP produced in and offered for sale in Korea. The home market price information in the industry report included inland freight to the customer in Korea; therefore, Petitioner deducted inland freight expenses to calculate ex-factory prices.[24]

Fair Value Comparisons

Based on the data provided by Petitioner, there is reason to believe that imports of DOTP from Korea are being, or are likely to be, sold in the United States at less-than-fair value. Based on comparisons of export price to NV in accordance with sections 772 and 773 of the Act, the estimated dumping margins for DOTP for Korea range from 23.70 to 47.86 percent.[25]

Initiation of Less-Than-Fair-Value Investigation

Based upon the examination of the AD Petition on DOTP from Korea, we find that the Petition meets the requirements of section 732 of the Act. Therefore, we are initiating a less-than-fair-value investigation to determine whether imports of DOTP from Korea are being, or are likely to be, sold in the United States at less-than-fair-value. In accordance with section 733(b)(1)(A) of the Act and 19 CFR 351.205(b)(1), unless postponed, we will make our preliminary determination no later than 140 days after the date of this initiation.

On June 29, 2015, the President of the United States signed into law the Trade Preferences Extension Act of 2015, which made numerous amendments to the AD and CVD law.[26] The 2015 law does not specify dates of application for those amendments. On August 6, 2015, the Department published an interpretative rule, in which it announced the applicability dates for each amendment to the Act, except for amendments contained in section 771(7) of the Act, which relate to determinations of material injury by the ITC.[27] The amendments to sections 771(15), 773, 776, and 782 of the Act are applicable to all determinations made on or after August 6, 2015, and, therefore, apply to this AD investigation.[28]

Respondent Selection

Petitioner named three companies as producers/exporters of DOTP from Korea.[29] Following the standard practice in AD investigations involving market economy countries, in the event the Department determines that the number of companies is large and it cannot individually examine each company based upon the Department's resources, the Department intends to select respondents based on U.S. Customs and Border Protection ("CBP") data for U.S. imports under the appropriate Harmonized Tariff Schedule of the United States ("HTSUS") numbers listed in the "Scope of Investigation" in Appendix I. We intend to release the CBP data under Administrative Protective Order ("APO") to all parties with access to information protected by APO within five business days of publication of this **Federal Register** notice. Comments regarding the CBP data and respondent selection should be submitted seven calendar days after the placement of the CBP data on the record of this investigation. Parties wishing to submit rebuttal comments should submit those comments five calendar days after the deadline for the initial comments.

Comments must be filed electronically using ACCESS. An electronically-filed document must be received successfully in its entirety by the Department's electronic records system, ACCESS, by 5 p.m. EDT, by the dates noted above. We intend to make our decision regarding respondent selection within 20 days of publication of this notice.

Distribution of Copies of the Petition

In accordance with section 732(b)(3)(A) of the Act and 19 CFR 351.202(f), a copy of the public version of the Petition has been provided to the government of Korea via ACCESS. To the extent practicable, we will attempt to provide a copy of the public version of the Petition to the exporters named in the Petition, as provided under 19 CFR 351.203(c)(2).

ITC Notification

We will notify the ITC of our initiation, as required by section 732(d) of the Act.

Preliminary Determination by the ITC

The ITC will preliminarily determine, within 45 days after the date on which the Petition was filed, whether there is a reasonable indication that imports of DOTP from Korea are materially injuring or threatening material injury to a U.S. industry.[30] A negative ITC determination will result in the investigation being terminated;[31] otherwise, the investigation will proceed according to statutory and regulatory time limits.

Submission of Factual Information

Factual information is defined in 19 CFR 351.102(b)(21) as: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by the Department; and (v) evidence other than factual information described in (i)–(iv). Any party, when submitting factual information, must specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted[32] and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct.[33] Time limits for the submission of factual information are addressed in 19 CFR 351.301, which provides specific time limits based on the type of factual information being submitted. Please review the regulations prior to submitting factual information in this investigation.

Extensions of Time Limits

Parties may request an extension of time limits before the expiration of a time limit established under 19 CFR 351, or as otherwise specified by the Secretary. In general, an extension request will be considered untimely if it is filed after the expiration of the time limit established under 19 CFR 351 expires. For submissions that are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. EDT on the due date. Under certain circumstances, we may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, we will inform parties in the letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. An extension request must be made in a separate, stand-alone submission; under limited circumstances we will grant untimely-filed requests for the extension of time limits. Review *Extension of Time Limits; Final Rule,* 78 FR 57790 (September 20, 2013), available at *http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm,* prior to submitting factual information in this investigation.

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[24] *Id.; see also* Petition, at Exhibit GEN–10.

[25] *See* Petition Supplement, at Exhibit Supp–3. *See also* AD Initiation Checklist.

[26] *See* Trade Preferences Extension Act of 2015, Public Law 114–27, 129 Stat. 362 (2015).

[27] *See Dates of Application of Amendments to the Antidumping and Countervailing Duty Laws Made by the Trade Preferences Extension Act of 2015,* 80 FR 46793 (August 6, 2015) (*Applicability Notice*).

[28] *Id.* at 46794–95. The 2015 amendments may be found at *https://www.congress.gov/bill/114th-congress/house-bill/1295/text/pl.*

[29] *See* Petition, at 3–4 and Exhibits GEN–7 and GEN–10.

[30] *See* section 733(a) of the Act.

[31] *Id.*

[32] *See* 19 CFR 351.301(b).

[33] *See* 19 CFR 351.301(b)(2).

Certification Requirements

Any party submitting factual information in an AD or countervailing duty ("CVD") proceeding must certify to the accuracy and completeness of that information.[34] Parties are hereby reminded that revised certification requirements are in effect for company/government officials, as well as their representatives. Investigations initiated on the basis of petitions filed on or after August 16, 2013, and other segments of any AD or CVD proceedings initiated on or after August 16, 2013, should use the formats for the revised certifications provided at the end of the *Final Rule.*[35] The Department intends to reject factual submissions if the submitting party does not comply with applicable revised certification requirements.

Notification to Interested Parties

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305. On January 22, 2008, the Department published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures,* 73 FR 3634 (January 22, 2008). Parties wishing to participate in this investigation should ensure that they meet the requirements of these procedures (*e.g.,* the filing of letters of appearance as discussed in 19 CFR 351.103(d)).

This notice is issued and published pursuant to section 777(i) of the Act.

Dated: July 20, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by this investigation is dioctyl terephthalate ("DOTP"), regardless of form. DOTP that has been blended with other products is included within this scope when such blends include constituent parts that have not been chemically reacted with each other to produce a different product. For such blends, only the DOTP component of the mixture is covered by the scope of this investigation.

DOTP that is otherwise subject to this investigation is not excluded when commingled with DOTP from sources not subject to this investigation. Commingled refers to the mixing of subject and non-subject DOTP. Only the subject component of such commingled products is covered by the scope of the investigation.

DOTP has the general chemical formulation $C_6H_4(C_8H_{17}COO)_2$ and a chemical name of "bis (2-ethylhexyl) terephthalate" and has a Chemical Abstract Service ("CAS") registry number of 6422–86–2. Regardless of the label, all DOTP is covered by this investigation.

Subject merchandise is currently classified under subheading 2917.39.2000 of the Harmonized Tariff Schedule of the United States ("HTSUS"). Subject merchandise may also enter under subheadings 2917.39.7000 or 3812.20.1000 of the HTSUS. While the CAS registry number and HTSUS classification are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

[FR Doc. 2016–17806 Filed 7–27–16; 8:45 am]

BILLING CODE 3510–DS–P

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[34] *See* section 782(b) of the Act.

[35] *See Certification of Factual Information to Import Administration during Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (*Final Rule*); *see also* frequently asked questions regarding the *Final Rule,* available at *http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–028]

Hydrofluorocarbon Blends and Components Thereof From the People's Republic of China: Notice of Correction to the Final Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

FOR FURTHER INFORMATION CONTACT: Dennis McClure, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–5973.

SUPPLEMENTARY INFORMATION: On June 29, 2016, the Department of Commerce (the Department) published in the **Federal Register** the final determination of sales at less than fair value (LTFV) in the antidumping duty investigation of hydrofluorocarbon blends and components thereof from the People's Republic of China.[1] In the *Final Determination,* the Department inadvertently assigned a weighted-average dumping margin of 101.82 percent to the following exporter/producer combinations: (1) Zhejiang Sanmei Chemical Industry Co., Ltd. (Zhejiang Sanmei Chemical Industry Co., Ltd.) and Zhejiang Sanmei Chemical Industry Co., Ltd. (Zhejiang Sanmei Chemical Industry Co., Ltd.); and (2) Zhejiang Sanmei Chemical Industry Co., Ltd. (Zhejiang Sanmei Chemical Industry Co., Ltd.) and Jiangsu Sanmei Chemicals Co., Ltd.[2] However, the weighted-average dumping margin should have been assigned, instead, to the following exporter/producer combinations, among others: (1) Zhejiang Sanmei Chemical Ind. Co. Ltd. (Zhejiang Sanmei Chemical Industry Co., Ltd.) and Zhejiang Sanmei Chemical Ind. Co., Ltd. (Zhejiang Sanmei Chemical Industry Co., Ltd.); and (2) Zhejiang Sanmei Chemical Ind. Co., Ltd. (Zhejiang Sanmei Chemical Industry Co., Ltd.) and Jiangsu Sanmei Chemicals Co., Ltd.[3] As a result, we now correct the final determination of sales at LTFV as noted above.

This correction to the final determination of sales at LTFV is issued and published in accordance with sections 735(a)(1) and 777(i)(1) of the Tariff Act of 1930, as amended.

Dated: July 20, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2016–17816 Filed 7–27–16; 8:45 am]

BILLING CODE 3510–DS–P

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[1] *See Hydrofluorocarbon Blends and Components Thereof From the People's Republic of China: Final Determination of Sales at Less Than Fair Value and Final Affirmative Determination of Critical Circumstances,* 81 FR 42314 (June 29, 2016) (*Final Determination*), and accompanying Issues and Decision Memorandum.

[2] *Id.,* 81 FR at 42316.

[3] *Id.,* at Comment 12.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE762

Fisheries of the Gulf of Mexico; Southeast Data, Assessment, and Review (SEDAR); Assessment Webinar for Gulf of Mexico Data-Limited Species

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of SEDAR 49 assessment Webinar II for Gulf of Mexico Data-limited Species.

SUMMARY: The SEDAR 49 assessment of the Gulf of Mexico Data-limited Species will consist of a data workshop, a review workshop, and a series of assessment Webinars.

DATES: The SEDAR 49 assessment Webinar II will be held on August 25, 2016, from 10 a.m. to 12 p.m., to view the agenda, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The Webinar is open to members of the public. Those interested in participating should contact Julie A. Neer at SEDAR (See Contact Information Below) to request an invitation providing Webinar access information. Please request Webinar invitations at least 24 hours in advance of each Webinar.

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Coordinator; (843) 571–4366 or email: *Julie.neer@safmc.net.*

SUPPLEMENTARY INFORMATION:

Agenda

The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a multi-step process including: (1) Data Workshop; (2) Assessment Process utilizing Webinars; and (3) Review Workshop. The product of the Data Workshop is a data report that compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report that describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, HMS Management Division, and Southeast Fisheries Science Center. Participants include data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and NGO's; International experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion in the Assessment Process Webinars are as follows:

1. Using datasets and initial assessment analysis recommended from the Data Workshop, panelists will employ assessment models to evaluate stock status, estimate population benchmarks and management criteria, and project future conditions.
2. Participants will recommend the most appropriate methods and configurations for determining stock status and estimating population parameters.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 10 business days prior to each workshop.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 22, 2016.

Tracey L. Thompson,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–17812 Filed 7–27–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Reporting Requirements for Sea Otter Interactions With the Pacific Sardine Fishery; Coastal Pelagic Species Fishery Management Plan

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before September 26, 2016.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Joshua Lindsay, (562) 980–4034 or *Joshua.Lindsay@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for extension of a currently approved information collection.

On May 30, 2007, the National Marine Fisheries Service (NMFS) published a Final Rule (72 FR 29891) implementing a requirement under the Coastal Pelagic Species Fishery Management Plan (CPS FMP) to report any interactions that may occur between a CPS vessel and/or fishing gear and sea otters.

Specifically, these reporting requirements are:

1. If a southern sea otter is entangled in a net, regardless of whether the animal is injured or killed, such an

occurrence must be reported within 24 hours to the Regional Administrator, NMFS West Coast Region.

2. While fishing for CPS, vessel operators must record all observations of otter interactions (defined as otters within encircled nets or coming into contact with nets or vessels, including but not limited to entanglement) with their purse seine net(s) or vessel(s). With the exception of an entanglement, which will be initially reported as described in #2 above, all other observations must be reported within 20 days to the Regional Administrator.

When contacting NMFS after an interaction, fishermen are required to provide information regarding the location, specifically latitude and longitude, of the interaction and a description of the interaction itself. Descriptive information of the interaction should include: Whether or not the otters were seen inside or outside the net; if inside the net, had the net been completely encircled; did contact occur with net or vessel; the number of otters present; duration of interaction; otter's behavior during interaction; and, measures taken to avoid interaction.

II. Method of Collection

The information will be collected on forms submitted by mail, phone, facsimile or email.

III. Data

OMB Control Number: 0648–0566.

Form Number(s): None.

Type of Review: Regular submission (extension of a currently approved collection).

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 2.

Estimated Time per Response: 15 minutes.

Estimated Total Annual Burden Hours: 1.

Estimated Total Annual Cost to Public: $10.00 in reporting costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: July 25, 2016.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2016–17880 Filed 7–27–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Scientific Integrity Office; Notice of Availability and Request for Public Comment

AGENCY: Office of Oceanic and Atmospheric Research (OAR), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of availability and request for public comment.

SUMMARY: NOAA Research (OAR) publishes this notice on behalf of the NOAA Scientific Integrity Office to announce the availability of the draft Procedural Handbook to accompany NOAA Administrative Order 202–735D, the scientific integrity policy, for public comment. The draft procedural handbook provides revised NOAA procedures to respond to allegations of scientific and research misconduct.

DATES: Comments on the draft Procedural Handbook must be received by August 29, 2016.

ADDRESSES: The draft Procedural Handbook is available on the NOAA Scientific Integrity Commons Web site at: *http://nrc.noaa.gov/ScientificIntegrityCommons.* The public is encouraged to submit comments electronically through *http://goo.gl/forms/v0uCTvbNo3ueWWc92.* For individuals who do not have access to the internet, comments may be submitted in writing to: NOAA Scientific Integrity Office c/o Patricia Hathaway, 1315 East-West Highway, Silver Spring, Maryland 20910.

FOR FURTHER INFORMATION CONTACT: Dr. Cynthia Decker, NOAA Scientific Integrity Officer, NOAA 1315 East-West Highway, Silver Spring, Maryland 20910. Phone: 301 734–1459, during normal business hours of 9 a.m. to 5 p.m. Eastern Time, Monday through Friday, or, visit the NOAA Scientific Integrity Commons at *http://nrc.noaa.gov/ScientificIntegrityCommons.*

SUPPLEMENTARY INFORMATION: The Presidential Memorandum on Scientific Integrity, the Office of Science and Technology Policy guidance memorandum on scientific integrity, and NOAA's 2011 Scientific Integrity policy call for the highest level of integrity in all aspects of the executive branch's involvement with scientific and technological processes. The draft Procedural Handbook that accompanies NOAA's Scientific Integrity Policy (in NOAA Administrative Order 202–735D) supports these principals by outlining how NOAA will respond to allegations of misconduct. The draft Procedural Handbook is a proposed revision of the original handbook put in place in 2011. This draft Procedural Handbook provides the revised procedures NOAA will follow in responding to allegations of Scientific and Research Misconduct by NOAA employees, NOAA contractors, and external recipients of NOAA financial assistance awards for scientific or research activities. This Procedural Handbook should be read in conjunction with NOAA's Scientific Integrity Policy in NOAA Administrative Order 202–735D.

Dated: July 25, 2016.

Jason Donaldson,

Chief Financial Officer, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 2016–17930 Filed 7–27–16; 8:45 am]

BILLING CODE 3510–KD–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB–2016–0026]

RIN 3170–AA40

Request for Information on Payday Loans, Vehicle Title Loans, Installment Loans, and Open-End Lines of Credit

Correction

In notice document 2016–13492, appearing on pages 47781 through 47789 in the issue of Friday, July 22, 2016, make the following correction:

On page 47781, in the second column, on the sixth line, "October 14, 2016" should read "November 7, 2016".

[FR Doc. C1–2016–13492 Filed 7–27–16; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID: USAF–2016–HQ–0004]

Privacy Act of 1974; System of Records

AGENCY: Department of the Air Force, DoD.

ACTION: Notice to delete a system of records.

SUMMARY: The Department of the Air Force proposes to delete one system of records notice from its inventory of record systems subject to the Privacy Act of 1974, as amended. The system of records notice is F035 AF SAFPA D, entitled "Your Guardians of Freedom User Database."

DATES: Comments will be accepted on or before August 29, 2016. This proposed action will be effective on the day following the end of the comment period unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

* *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

* *Mail:* Department of Defense, Office of the Deputy Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Mr. LaDonne L. White, Department of the Air Force Privacy Office, Air Force Privacy Act Office, Office of Warfighting Integration and Chief Information Officer, ATTN: SAF/CIO A6, 1800 Air Force Pentagon, Washington, DC 20330–1800, or by phone at (571) 256–2515.

SUPPLEMENTARY INFORMATION: The Department of the Air Force systems of records notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT** or at the Defense Privacy, Civil Liberties and Transparency Division Web site at *http://dpcld.defense.gov/.* The Department of the Air Force proposes to delete one system of records notice from its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended. The proposed deletion is not within the purview of subsection (r) of the Privacy Act of 1974 (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: July 25, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

Deletion:
F035 AF SAFPA D

Your Guardians of Freedom User Database (November 18, 2003, 68 FR 65038)

Reason: SAF/PA no longer maintains the Your Guardians of Freedom database. The program ended in 2006 and the database was decommissioned. The records retention period was for one year (2007), after which all remaining records were deleted in 2008.

[FR Doc. 2016–17871 Filed 7–27–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army, U.S. Army Corps of Engineers

Withdrawal of Notice of Intent To Prepare an Environmental Impact Statement for Western Lake Erie Basin, Blanchard River Watershed Study

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DoD.

ACTION: Notice of withdrawal.

SUMMARY: The purpose of this notice is to inform the public that the non-Federal sponsor (Hancock County, Ohio) for the Blanchard River Watershed Study has decided to complete the design and construction of the proposed project. Therefore, the current NEPA process with the Corps of Engineers acting as the lead agency has been terminated, and notice to prepare an Environmental Impact Statement (EIS) and notice of availability are withdrawn.

FOR FURTHER INFORMATION CONTACT: Michael D. Pniewski, Project Manager, 1776 Niagara Street, Buffalo, NY 14207–3199, Telephone 419–726–9121; electronic mail: *Michael.D.Pniewski@usace.army.mil.*

SUPPLEMENTARY INFORMATION: On November 30, 2012, (77 FR 71404), the United States Army Corps of Engineers (USACE) in partnership with Hancock County (County) announced its intent to prepare an EIS in accordance with the National Environmental Policy Act of 1969 (NEPA) to evaluate proposed flood risk management and riparian wetland habitat restoration measures in the Blanchard River Watershed in the vicinity of the city of Findlay, Ohio. On April 10, 2015 (80 FR 19316), USACE and the County announced the availability of the Draft EIS (EIS No. 20150102). The Draft EIS evaluated the potential environmental impacts associated with the proposed Federal action and its reasonable alternatives. The purpose of the project was to reduce the risk of flooding and improve the overall quality of life for the residents of the Findlay area. Subsequent to the release of the Draft Detailed Project Report and EIS, the County has decided to proceed with the design and construction of the project without USACE involvement.

Adam J. Czekanski,

Lieutenant Colonel, Corps of Engineers, District Engineer.

[FR Doc. 2016–17828 Filed 7–27–16; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2484–018; 2464–015]

Gresham Municipal Utilities; Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission or FERC) regulations, 18 CFR part 380 (Order No. 486, 52 **Federal Register** 47897), the Office of Energy Projects has reviewed applications for subsequent licenses for the Upper Red Lake Dam Hydroelectric Project (FERC Project No. 2484–018) and the Weed Dam Hydroelectric Project (FERC Project No. 2464–015), located on the Red River in Shawano County, Wisconsin. The projects do not occupy federal land.

The environmental assessment analyzes the potential environmental effects of continuing to operate the projects, and concludes that issuing subsequent licenses for the projects, with appropriate environmental measures, would not constitute a major federal action significantly affecting the quality of the human environment.

A copy of the EA is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the "eLibrary" link. Enter either docket number, excluding the last three digits in the docket number field, to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* at (866) 208–3676 (toll free), or (202) 502–8659 (TTY).

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to these or other pending projects. For assistance, contact FERC Online Support.

Any comments should be filed within 30 days from the date of this notice. The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support.

Although the Commission strongly encourages electronic filing, documents may also be paper-filed. In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. Please put docket number(s) "P–2464–015" and/or "P–2484–018," as appropriate, on the first page of your response.

For further information, please contact Chelsea Hudock by phone at (202) 502–8448, or by email at *chelsea.hudock@ferc.gov.*

Dated: July 21, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–17852 Filed 7–27–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. P–13212–005; Project No. P–13212–005]

Kenai Hydro, LLC ; Notice of Scoping Meetings and Environmental Site Review and Soliciting Scoping Comments

Take notice that the following hydroelectric application has been filed with Commission and is available for public inspection:

a. *Type of Application:* Application for Original License for Major Project—Unconstructed.

b. *Project No.:* 13212–005.

c. *Date filed:* April 18, 2016.

d. *Applicant:* Kenai Hydro, LLC.

e. *Name of Project:* Grant Lake Hydroelectric Project.

f. *Location:* On Grant Creek, near the Town of Moose Pass, Kenai Peninsula Borough, Alaska. The proposed project would occupy 1,741.3 acres of federal land within the Chugach National Forest managed by the U.S. Forest Service.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mike Salzetti, Manager of Fuel Supply & Renewable Energy Development, 280 Airport Way, Kenai, AK 99611. (907) 283–2375.

i. *FERC Contact:* Kenneth Hogan, *kenneth.hogan@ferc.gov,* 202–502–8434.

j. *Deadline for filing scoping comments:* October 10, 2016.

The Commission strongly encourages electronic filing. Please file scoping comments using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–13212–005.

The Commission's Rules of Practice and Procedure require all interveners filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application is not ready for environmental analysis at this time.

l. The proposed Grant Lake Hydroelectric Project would consist of: (1) An intake structure within Grant Lake; (2) a 3,300-foot-long tunnel; (3) a 72-inch-diameter, 150-foot-long, steel penstock; (4) a power house containing two 2.5-megawatt Francis turbine/generator units; (5) a 95-foot-long open channel tailrace; (6) a 3.6-acre tailrace detention pond; (6) a 1.1-mile-long, 115-kilovolt transmission line; (7) two miles of project access road; and (8) appurtenant facilities.

m. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support. Copies are also available for inspection and reproduction at the Kenai Community Library at 163 Main St Loop, Kenai, AK 99611 and at the Homer Electric Office at 280 Airport Way, Kenai, AK 99611.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. *Scoping Process:*

The Commission intends to prepare an Environmental assessment (EA) on the project in accordance with the National Environmental Policy Act. The EA will consider both site-specific and cumulative environmental impacts and reasonable alternatives to the proposed action.

Scoping Meetings

FERC staff will conduct one agency scoping meeting and one public meeting. The agency scoping meeting will be held during business hours and will focus on resource agency and non-governmental organization (NGO) concerns, while the public scoping meeting is primarily for public input and will be held in the evening. All interested individuals, organizations, and agencies are invited to attend one or both of the meetings, and to assist the staff in identifying the scope of the environmental issues that should be analyzed in the EA. The times and locations of these meetings are as follows:

Evening Scoping Meeting

Date and Time: Wednesday, September 7, at 7:00 p.m. (Local Time).

Location: Moose Pass Community Hall, Mile 29.5 Seward Highway, Moose Pass, AK 99631.

Daytime Scoping Meeting

Date and Time: Thursday, September 8, at 10:00 a.m. (Local Time).

Location: Moose Pass Community Hall, Mile 29.5 Seward Highway, Moose Pass, AK 99631.

Copies of the Scoping Document (SD3) outlining the subject areas to be addressed in the EA were distributed to the parties on the Commission's mailing list and to Kenai Hydro's distribution list. Copies of the SD3 will be available at the scoping meetings and may be viewed on the Web at *http://www.ferc.gov* using the "eLibrary" link (see item m above).

Environmental Site Review

The Applicant and FERC staff will conduct a project Environmental Site Review beginning at 8:00 a.m. on September 7, 2016. All participants interested in the environmental site review and hiking into the location of the proposed powerhouse should meet at the Moose Pass Community Hall on the Seward Highway at mile 29.5 by 8 a.m. on September 7, 2016. Participants should be in good health and prepared/able to hike without assistance for 5 miles in unimproved trail conditions with a 200 yard section of off trail hiking in a heavily forested area. The elevation gain for the hike is approximately 200 feet. Participants should also pack their own lunch, snacks and water, wear rugged footwear, and be prepared for inclement and potentially cold weather conditions. Anyone with questions about the site visit should contact Mike Salzetti at (907) 283–2375 or *msalzetti@homerelectric.com.* Those individuals planning to participate in the site visit should notify Mr. Salzetti of their intent, no later than August 26, 2016.

Objectives

At the scoping meetings, the staff will: (1) Summarize the environmental issues tentatively identified for analysis in the EA; (2) solicit from the meeting participants all available information, especially quantifiable data, on the resources at issue; (3) encourage statements from experts and the public on issues that should be analyzed in the EA, including viewpoints in opposition to, or in support of, the staff's preliminary views; (4) determine the resource issues to be addressed in the EA; and (5) identify those issues that require a detailed analysis, as well as those issues that do not require a detailed analysis.

Procedures

The meetings are recorded by a stenographer and become part of the formal record of the Commission proceeding on the project.

Individuals, organizations, and agencies with environmental expertise and concerns are encouraged to attend the meeting and to assist the staff in defining and clarifying the issues to be addressed in the EA.

Dated: July 22, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–17855 Filed 7–27–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL16–99–000]

Midcontinent Independent System Operator, Inc.; Notice of Institution of Section 206 Proceeding and Refund Effective Date

On July 21, 2016, the Commission issued an order in Docket No. EL16–99–000, pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e (2012), instituting an investigation into the justness and reasonableness of the Midcontinent Independent System Operator, Inc.'s Transmission, Energy and Operating Reserve Markets Tariff. *Midcontinent Independent System Operator, Inc.,* 156 FERC ¶ 61,061 (2016).

The refund effective date in Docket No. EL16–99–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register**.

Dated: July 21, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–17836 Filed 7–27–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM16–17–000]

Data Collection for Analytics and Surveillance and Market-Based Rate Purposes; Notice of the Technical Workshop on the Draft Data Dictionary Attached to the Data Collection for Analytics and Surveillance and Market-Based Rate Purposes Notice of Proposed Rulemaking

The Notice of Proposed Rulemaking on Data Collection for Analytics and Surveillance and Market-Based Rate Purposes (NOPR) issued today in Docket No. RM16–17 proposes to revise the Commission's regulations to collect certain data for analytics and surveillance purposes from market-based rate (MBR) sellers and entities trading virtual products or holding financial transmission rights and to change certain aspects of the substance and format of information submitted for MBR purposes.[1] In the NOPR, the Commission also states that a data dictionary posted to the Commission's Web site would define the framework to be followed by users in submitting information for inclusion in the relational database and that staff will hold technical workshops on the data dictionary and the submittal process.[2] This notice announces a technical workshop to review the draft data dictionary attached to the NOPR.

All interested parties are invited to attend. The workshop will be held in Washington, DC, on August 11, 2016 from 9:00 a.m. to 4:00 p.m. at FERC headquarters in the Commission Meeting Room, 888 First Street NE., Washington, DC. For those unable to attend in person, access to the workshop sessions will be available by webcast.

The workshop is intended to provide a forum for interactive, detailed discussion of the elements contained in the sample data dictionary. Commission staff will lead the workshop. The agenda for the workshop is attached. Notes from the workshop will be posted on *FERC.gov.*

Due to the detailed, substantive nature of the subject matter, parties interested in actively participating in the discussion are encouraged to attend in person. All interested parties (whether attending in person or via webcast) are asked to register online at *https://www.ferc.gov/whats-new/registration/08-11-16-form.asp.* There is no registration fee.

Those wishing to actively participate in the discussion by telephone during the workshop should send a request for a telephone line to *RM16-17.NOPR@ferc.gov* by close of business on Friday, August 5th, with the subject line: RM16–17 NOPR Workshop Teleconference Request.

Commission workshops are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations please send an email to *accessibility@ferc.gov* or call toll free 1–866–208–3372 (voice) or 202–502–8659 (TTY); or send a fax to 202–208–2106 with the required accommodations.

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[1] *Data Collection for Analytics and Surveillance and Market-Based Rate Purposes,* 156 FERC ¶61, 045 (2016).

[2] *Id.* at P 15.

For additional information, please contact David Pierce of FERC's Office of Enforcement at (202) 502–6454 or send an email to *RM16-17.NOPR@ferc.gov.*

Dated: July 21, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–17857 Filed 7–27–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL16–91–000]

Southwest Power Pool, Inc.; Notice of Institution of Section 206 Proceeding and Refund Effective Date

On July 21, 2016, the Commission issued an order in Docket No. EL16–91–000, pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e (2012), instituting an investigation into the justness and reasonableness of certain aspects of Southwest Power Pool, Inc.'s Open Access Transmission Tariff. *Southwest Power Pool, Inc.,* 156 FERC ¶ 61,059 (2016).

The refund effective date in Docket No. EL16–91–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register**.

Dated: July 21, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–17851 Filed 7–27–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC16–155–000.
Applicants: Odell Wind Farm, LLC, Algonquin Power (Odell Holdings) Inc., Odell SponsorCo, LLC, Odell Holdings, LLC, Enel Kansas, LLC.
Description: Application for Authorization Under Section 203 of the Federal Power Act for the Disposition of Jurisdictional Facilities, Request for Expedited Consideration and Confidential Treatment of Odell Wind Farm, LLC, et al.
Filed Date: 7/22/16.
Accession Number: 20160722–5116.
Comments Due: 5 p.m. ET 8/12/16.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–3246–002; ER10–2475–006; ER10–2474–006.
Applicants: PacifiCorp, Nevada Power Company, Sierra Pacific Power Company.
Description: The BHE Renewables Companies submit tariff filing per 35.19a(b): Refund Report to be effective N/A.
Filed Date: 7/21/16.
Accession Number: 20160721–5130.
Comments Due: 5 p.m. ET 8/11/16.

Docket Numbers: ER14–1548–007.
Applicants: Copper Mountain Solar 3, LLC.
Description: Compliance Filing reflecting results of Commission determination with regard to horizontal market power analysis in the APS Triennial Proceeding of Copper Mountain Solar 3, LLC.
Filed Date: 10/15/14.
Accession Number: 20141015–5184.
Comments Due: 5 p.m. ET 8/1/16.

Docket Numbers: ER15–13–006.
Applicants: Transource Wisconsin, LLC.
Description: Compliance filing: Transource Wisconsin Formula Compliance Filing to be effective 12/1/2014.
Filed Date: 7/22/16.
Accession Number: 20160722–5074.
Comments Due: 5 p.m. ET 8/12/16.

Docket Numbers: ER16–1832–001.
Applicants: Entergy Louisiana, LLC.
Description: Tariff Amendment: ELL Nine Mile 6 Supplemental Reactive to be effective 8/1/2016.
Filed Date: 7/22/16.
Accession Number: 20160722–5082.
Comments Due: 5 p.m. ET 8/12/16.

Docket Numbers: ER16–2007–000.
Applicants: Saguaro Power Company, a Limited Partnership.
Description: Supplement to June 24, 2016 Saguaro Power Company, a Limited Partnership submits tariff filing.
Filed Date: 7/21/16.
Accession Number: 20160721–5129.
Comments Due: 5 p.m. ET 8/11/16.

Docket Numbers: ER16–2135–001.
Applicants: Terrapin Energy LLC.
Description: Tariff Amendment: Amendment to Application for MBR to be effective 9/1/2016.
Filed Date: 7/22/16.
Accession Number: 20160722–5136.
Comments Due: 5 p.m. ET 8/12/16.

Docket Numbers: ER16–2265–000.
Applicants: C.P. Crane LLC.
Description: § 205(d) Rate Filing: Reactive Rate Tariff to be effective 1/5/2016.
Filed Date: 7/22/16.
Accession Number: 20160722–5069.
Comments Due: 5 p.m. ET 8/12/16.

Docket Numbers: ER16–2266–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2016–07–22_SA 2931 ATC-Wisconsin Power and Light E&P (J390) to be effective 7/23/2016.
Filed Date: 7/22/16.
Accession Number: 20160722–5081.
Comments Due: 5 p.m. ET 8/12/16.

Docket Numbers: ER16–2267–000.
Applicants: Southwestern Public Service Company.
Description: § 205(d) Rate Filing: SPS–RBEC–GSEC–649 0.1.0–NOC to be effective 9/21/2016.
Filed Date: 7/22/16.
Accession Number: 20160722–5094.
Comments Due: 5 p.m. ET 8/12/16.

Docket Numbers: ER16–2268–000.
Applicants: Arizona Public Service Company.
Description: Compliance filing: OATT Modification Pursuant to Order No. 827 to be effective 9/21/2016.
Filed Date: 7/22/16.
Accession Number: 20160722–5096.
Comments Due: 5 p.m. ET 8/12/16.

Docket Numbers: ER16–2269–000.
Applicants: Southern California Edison Company.
Description: § 205(d) Rate Filing: Amended LGIA Chevron Power Holdings Kern River Cogeneration Facility Project to be effective 7/23/2016.
Filed Date: 7/22/16.
Accession Number: 20160722–5098.
Comments Due: 5 p.m. ET 8/12/16.

Docket Numbers: ER16–2270–000.
Applicants: Pinetree Power-Tamworth, LLC.
Description: § 205(d) Rate Filing: Notice of Succession to be effective 9/21/2016.
Filed Date: 7/22/16.
Accession Number: 20160722–5139.
Comments Due: 5 p.m. ET 8/12/16.

Docket Numbers: ER16–2271–000.
Applicants: ENGIE Resources LLC.
Description: § 205(d) Rate Filing: Notice of Succession to be effective 9/21/2016.
Filed Date: 7/22/16.
Accession Number: 20160722–5143.
Comments Due: 5 p.m. ET 8/12/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's

Regulations (18 CFR 385.211 and § 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 22, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–17877 Filed 7–27–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD16–2–000]

Billing Procedures for Annual Charges for the Costs of Other Federal Agencies for Administering Part I of the Federal Power Act; Notice Reporting Costs for Other Federal Agencies' Administrative Annual Charges for Fiscal Year 2015

1. The Federal Energy Regulatory Commission (Commission) is required to determine the reasonableness of costs incurred by other Federal agencies (OFAs)[1] in connection with their participation in the Commission's proceedings under the Federal Power Act (FPA) Part I[2] when those agencies seek to include such costs in the administrative charges licensees must pay to reimburse the United States for the cost of administering Part I.[3] The Commission's *Order on Remand and Acting on Appeals of Annual Charge Bills*[4] determined which costs are eligible to be included in the administrative annual charges and it established a process for Commission review of future OFA cost submittals. This order established a process whereby the Commission would annually request each OFA to submit cost data, using a form[5] specifically designed for this purpose. In addition, the order established requirements for detailed cost accounting reports and other documented analyses, which explain the cost assumptions contained in the OFAs' submissions.

2. The Commission has completed its review of the forms and supporting documentation submitted by the U.S. Department of the Interior (Interior), the U.S. Department of Agriculture (Agriculture), and the U.S. Department of Commerce (Commerce) for fiscal year 2015. This notice reports the costs the Commission included in its administrative annual charges for fiscal year 2016.

Scope of Eligible Costs

3. The basis for eligible costs that should be included in the OFAs' administrative annual charges is prescribed by the Office of Management and Budget's (OMB) Circular A–25—*User Charges* and the Federal Accounting Standards Advisory Board's Statement of Federal Financial Accounting Standards (SFFAS) Number 4—*Managerial Cost Accounting Concepts and Standards for the Federal Government.* Circular A–25 establishes Federal policy regarding fees assessed for government services and provides specific information on the scope and type of activities subject to user charges. SSFAS Number 4 provides a conceptual framework for federal agencies to determine the full costs of government goods and services.

4. Circular A–25 provides for user charges to be assessed against recipients of special benefits derived from federal activities beyond those received by the general public.[6] With regard to licensees, the special benefit derived from federal activities is the license to operate a hydropower project. The guidance provides for the assessment of sufficient user charges to recover the *full* costs of services associated with these special benefits.[7] SFFAS Number 4 defines full costs as the costs of resources consumed by a specific governmental unit that contribute directly or indirectly to a provided service.[8] Thus, pursuant to OMB requirements and authoritative accounting guidance, the Commission must base its OFA administrative annual charge on all direct and indirect costs incurred by agencies in administering Part I of the FPA. The special form the Commission designed for this purpose, the "Other Federal Agency Cost Submission Form," captures the full range of costs recoverable under the FPA and the referenced accounting guidance.[9]

Commission Review of OFA Cost Submittals

5. The Commission received cost forms and other supporting documentation from the Departments of the Interior, Agriculture, and Commerce (OFAs). The Commission completed a review of each OFA's cost submission forms and supporting reports. In its examination of the OFAs' cost data, the Commission considered each agency's ability to demonstrate a system or process which effectively captured, isolated, and reported Part I costs as required by the "Other Federal Agency Cost Submission Form."

6. The Commission held a Technical Conference on April 7, 2016 to report its initial findings to licensees and OFAs. Representatives for several licensees and most of the OFAs attended the conference. Following the technical conference, a transcript was posted, and licensees had the opportunity to submit comments[10] to the Commission regarding its initial review.

7. Written comments were filed by Idaho Falls Group (Idaho Falls). Idaho Falls generally supported the Commission's analysis but raised questions regarding certain various individual cost submissions. The Commission will address the issues raised in the Appendix to this notice.

8. After additional reviews, full consideration of the comments presented, and in accordance with the previously cited guidance, the Commission accepted as reasonable any costs reported via the cost submission forms that were clearly documented in the OFAs' accompanying reports and/or analyses. These documented costs will be included in the administrative annual charges for fiscal year 2016.

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[1] The OFAs include: The U.S. Department of the Interior (Bureau of Indian Affairs, Bureau of Land Management, Bureau of Reclamation, National Park Service, U.S. Fish and Wildlife Service, Office of the Solicitor, Office of Environmental Policy & Compliance, Office of Hearings and Appeals and Office of Policy Analysis); the U.S. Department of Agriculture (U.S. Forest Service); the U.S. Department of Commerce (National Marine Fisheries Service); and the U.S. Army Corps of Engineers.

[2] 16 U.S.C. 794–823d (2012).

[3] *See id.* 803(e)(1) and 42 U.S.C. 7178.

[4] 107 FERC ¶ 61,277, *order on reh'g,* 109 FERC ¶ 61,040 (2004).

[5] Other Federal Agency Cost Submission Form, *available at https://www.ferc.gov/docs-filing/forms.asp#ofa.*

[6] OMB Circular A–25 § 6.

[7] OMB Circular A–25 § 6.a.2.

[8] SFFAS Number 4 ¶ 7.

[9] To avoid the possibility of confusion that has occurred in prior years as to whether costs were being entered twice as "Other Direct Costs" and "Overhead," the form excluded "Other Direct Costs."

[10] *See* Letter from Charles R. Sensiba, Van Ness Feldman, to the Honorable Kimberly D. Bose, FERC, Docket No. AD16–2–000 (filed May 13, 2016).

SUMMARY OF REPORTED & ACCEPTED COSTS FOR FISCAL YEAR 2015

[Figure 1]

	Municipal		Non-municipal		Total	
	Reported	Accepted	Reported	Accepted	Reported	Accepted
Department of Interior						
Bureau of Indian Affairs	273,348	214,243	385,922	334,374	659,270	548,617
Bureau of Land Management	162,847	159,428	5,007	3,089	167,854	162,517
Bureau of Reclamation			20,680	20,680	20,680	20,680
National Park Service	301,785	301,785	480,652	480,651	782,437	782,437
U.S. Fish and Wildlife Service	754,732	753,664	938,031	933,919	1,692,763	1,687,582
U.S. Geological Survey						
Office of the Solicitor	5,684	5,684	110,699	110,699	116,383	116,383
Office of the Environmental Policy & Compliance	47,054	47,054	106,266	106,266	153,320	153,320
Office of Hearings and Appeals	763		2,997		3,760	
Office of Policy Analysis						
Department of Agriculture						
U.S. Forest Service	653,758	611,610	1,443,838	1,351,324	2,097,586	1,962,933
Department of Commerce						
National Marine Fisheries Service	1,142,203	948,320	789,673	449,589	1,931,876	1,397,909
Total	3,342,174	3,041,788	4,283,755	3,790,592	7,625,929	6,832,378

9. Figure 1 summarizes the total reported costs incurred by Interior, Agriculture, and Commerce with respect to each OFA's participation in administering Part I of the FPA. Additionally, Figure 1 summarizes the reported costs that the Commission determined were clearly documented and accepted for inclusion in its FY 2016 administrative annual charges.

Summary Findings of Commission's Costs Review

10. As presented in the preceding table, the Commission determined that $6,832,378 of the $7,625,929 in total reported costs were determined to be reasonable and clearly documented in the OFAs' accompanying reports and/or analyses. Based on these findings, 10% of the total reported cost was determined to be unreasonable. The Commission noted the most significant issues with regard to the insufficiency of documentation provided by the OFAs was the lack of supporting documentation to substantiate costs reported on the "Other Federal Agency Cost Submission Form" as well as the failure to segregate Municipal and Non-Municipal costs.

11. The cost reports that the Commission determined were clearly documented and supported could be traced to detailed cost-accounting reports, which reconciled to data provided from agency financial systems or other pertinent source documentation. A further breakdown of these costs is included in the Appendix to this notice, along with an explanation of how the Commission determined their reasonableness.

Points of Contact

12. If you have any questions regarding this notice, please contact Norman Richardson at (202) 502–6219 or Raven Rodriquez at (202) 502–6276.

Dated: July 21, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–17850 Filed 7–27–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2426–049]

California Department of Water Resources; Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Recreation Plan.

b. *Project No:* 2426–049.

c. *Date Filed:* May 20, 2016.

d. *Applicant:* California Department of Water Resources.

e. *Name of Project:* South SWP Hydroelectric Project.

f. *Location:* The project is located on the California Aqueduct in San Bernardino, Los Angeles, San Luis Obispo, Ventura, and Kern counties, California and occupies, in part, federal lands administered by the United States Forest Service.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Bonnie Duecker, California Department of Water Resources, 34534 116th Street East, Pearblossom, CA 93553, (661) 944–8557, *Bonnie.Duecker@water.ca.gov.*

i. *FERC Contact:* Dr. Mark Ivy, (202) 502–6156, *mark.ivy@ferc.gov.*

j. *Deadline for filing comments, motions to intervene, and protests:* August 22, 2016.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal

Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–2426–049.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Request:* California Department of Water Resources requests Commission approval of a proposed recreation plan for the project. The recreation plan provides a detailed description of all existing recreation amenities and facilities in the immediate vicinity of Pyramid Lake, Silverwood Lake, and Quail Lake, which are components of the project. The recreation plan also includes visitation data, concessionaire reports, and site plan drawings.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title "COMMENTS", "PROTEST", or "MOTION TO INTERVENE" as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Dated: July 22, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–17859 Filed 7–27–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM16–18–000]

Cyber Systems in Control Centers

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Notice of Inquiry.

SUMMARY: In this Notice of Inquiry, the Federal Energy Regulatory Commission seeks comment on possible modifications to the Critical Infrastructure Protection Reliability Standards regarding the cybersecurity of Control Centers used to monitor and control the bulk electric system in real time.

DATES: Comments are due September 26, 2016.

ADDRESSES: You may submit comments, identified by docket number and in accordance with the requirements posted on the Commission's Web site, *http://www.ferc.gov.* Comments may be submitted by any of the following methods:

- *Agency Web site:* Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format, at *http://www.ferc.gov/docs-filing/efiling.asp.*
- *Mail/Hand Delivery:* Those unable to file electronically must mail or hand deliver comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

Instructions: For detailed instructions on submitting comments and additional information on the rulemaking process, see the Comment Procedures Section of this document.

FOR FURTHER INFORMATION CONTACT:

David DeFalaise (Technical Information), Office of Electric Reliability, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–8180, *David.DeFalaise@ferc.gov*

Robert T. Stroh (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–8473, *Robert.Stroh@ferc.gov*

SUPPLEMENTARY INFORMATION:

1. In this Notice of Inquiry, pursuant to section 215 of the Federal Power Act (FPA),[1] the Commission seeks comment on the need for, and possible effects of, modifications to the Critical Infrastructure Protection (CIP) Reliability Standards regarding the cybersecurity of Control Centers used to monitor and control the bulk electric system in real time.[2] Cyber systems are used extensively for the operation and maintenance of interconnected transmission networks.[3] A 2015

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[1] 16 U.S.C. 824o. Section 215(a)(3) of the FPA defines "Reliability Standard" to include ". . . requirements for the operation of existing bulk-power system facilities, including cybersecurity protection . . ."

[2] NERC defines "Control Center" as "[o]ne or more facilities hosting operating personnel that monitor and control the Bulk Electric System (BES) in realtime to perform the reliability tasks, including their associated data centers . . . ." NERC Glossary of Terms Used in Reliability Standards (May 17, 2016) at 33 (NERC Glossary).

[3] Cyber systems are referred to as "BES Cyber Systems" in the CIP Reliability Standards. The NERC Glossary defines BES Cyber Systems as "One or more BES Cyber Assets logically grouped by a responsible entity to perform one or more reliability tasks for a functional entity." NERC Glossary at 15. The NERC Glossary defines "BES Cyber Asset" as "A Cyber Asset that if rendered unavailable, degraded, or misused would, within 15 minutes of its required operation, misoperation, or non-operation, adversely impact one or more Facilities, systems, or equipment, which, if destroyed, degraded, or otherwise rendered unavailable when needed, would affect the reliable operation of the Bulk Electric System. Redundancy of affected Facilities, systems, and equipment shall not be considered when determining adverse impact. Each

Continued

cyberattack on the electric grid in Ukraine is an example of how cyber systems used to operate and maintain interconnected networks, unless adequately protected, may be vulnerable to cyberattack. While certain controls in the CIP Reliability Standards may reduce the risk of such attacks,[4] the Commission seeks comment on whether additional controls should be required.

2. Specifically, as discussed below, the Commission seeks comment on possible modifications to the CIP Reliability Standards—and any potential impacts on the operation of the Bulk-Power System resulting from such modifications—to address the following matters: (1) Separation between the Internet and BES Cyber Systems in Control Centers performing transmission operator functions; and (2) computer administration practices that prevent unauthorized programs from running, referred to as "application whitelisting," for cyber systems in Control Centers.

I. Background

3. On January 28, 2008, the Commission approved an initial set of eight CIP Reliability Standards pertaining to cybersecurity.[5] In addition, the Commission directed NERC to develop certain modifications to the CIP Reliability Standards. Since 2008, the CIP Reliability Standards have undergone multiple revisions to address Commission directives and respond to emerging cybersecurity issues.

4. On December 23, 2015, three regional electric power distribution companies in Ukraine experienced a cyberattack resulting in power outages that affected at least 225,000 customers. An analysis conducted by a team from the Electricity Information Sharing and Analysis Center (E–ISAC) and SANS Industrial Control Systems (SANS ICS) observed that "the cyber attacks in Ukraine are the first publicly acknowledged incidents to result in power outages."[6]

5. On February 25, 2016, the U.S. Department of Homeland Security (DHS) Industrial Control Systems Cyber Emergency Response Team issued an "Alert" in response to the Ukraine incident.[7] The Alert stated that the cyberattack was sophisticated and well planned. The Alert reported that the cyberattacks at each company occurred within 30 minutes of each other and affected multiple central and regional facilities. The Alert also explained that during the cyberattacks:

> malicious remote operation of the breakers was conducted by multiple external humans using either existing remote administration tools at the operating system level or remote industrial control system (ICS) client software via virtual private network (VPN) connections. The companies believe that the actors acquired legitimate credentials prior to the cyber-attack to facilitate remote access.

In addition, the Alert reported that the affected companies indicated that the attackers wiped some systems at the conclusion of the cyberattack, which erased selected files, rendering systems inoperable.

6. In response to the Ukraine incident, the Alert recommended the following key examples of best practice mitigation strategies:

> procurement and licensing of trusted hardware and software systems; knowing who and what is on your network through hardware and software asset management automation; on time patching of systems; and strategic technology refresh.[8]

II. Request for Comments

7. The Commission seeks comment on whether to modify the CIP Reliability Standards to better secure Control Centers from cyberattacks. The Commission also seeks comment on the potential consequences or complications arising from implementing such modifications. In response to lessons learned from the Alert and analyses of the Ukraine incident, the Commission seeks comment on whether to modify the CIP Reliability Standards to require: (1) Separation between the Internet and BES Cyber Systems in Control Centers performing transmission operator functions; and (2) "application whitelisting" for BES Cyber Systems in Control Centers.

A. Isolation of Transmission Operator Control Centers From the Internet

8. In response to the Ukraine incident, the Alert recommended that:

> [o]rganizations should isolate [industrial control system] networks from any untrusted networks, especially the Internet. All unused ports should be locked down and all unused services turned off. If a defined business requirement or control function exists, only allow real-time connectivity to external networks. If one-way communication can accomplish a task, use optical separation ('data diode'). If bidirectional communication is necessary, then use a single open port over a restricted network path.

9. Commission-approved Reliability Standard CIP–007–6, Requirement R1 (Ports and Services), Part 1.1 requires, where technically feasible, unused logical ports to be disabled.[9] In addition, Reliability Standard CIP–007–6, Requirement R1, Part 1.2 requires protection of physical ports against unnecessary use.[10] These requirements therefore address the Alert's recommendation that "[a]ll unused ports should be locked down and all unused services turned off."

10. The current CIP Reliability Standards do not require isolation between the Internet and BES Cyber Systems in Control Centers performing transmission operator functions through use of physical (hardware) or logical (software) means. Although BES Cyber Systems are protected by electronic security perimeters and the disabling of unused logical ports, BES Cyber Systems are permitted, within the scope of the current CIP Reliability Standards, to route, or connect, to the Internet.[11] Requiring physical separation between the Internet and cyber systems in Control Centers performing transmission operator functions would require data connections to Control Centers or other facilities owned by transmission operators over dedicated data lines owned or leased by the transmission operator, rather than allowing communications over the

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BES Cyber Asset is included in one or more BES Cyber Systems." *Id.*

[4] *See, e.g.,* Reliability Standard CIP–005–5 (Electronic Security Perimeter(s)), Requirement R2, which protects against unauthorized interactive remote access; Reliability Standard CIP–006–6 (Physical Security of BES Cyber Systems), Requirement R2, which protects against unauthorized physical access and Reliability Standard CIP–007–6 (System Security Management), Requirement R3, which protects against malware.

[5] *Mandatory Reliability Standards for Critical Infrastructure Protection,* Order No. 706, 122 FERC ¶ 61,040, *denying reh'g and granting clarification,* Order No. 706–A, 123 FERC ¶ 61,174 (2008), *order on clarification,* Order No. 706–B, 126 FERC ¶ 61,229 (2009), *order denying clarification,* Order No. 706–C, 127 FERC ¶ 61,273 (2009).

[6] E–ISAC, Analysis of the Cyber Attack on the Ukrainian Power Grid (March 18, 2016) at 3, *http://www.nerc.com/pa/CI/ESISAC/Documents/E-ISAC_SANS_Ukraine_DUC_18Mar2016.pdf.*

[7] *See* Department of Homeland Security, Alert (IR–ALERT–H–16–056–01) *Cyber-Attack Against Ukrainian Critical Infrastructure* (February 25, 2016) (Alert), *https://ics-cert.us-cert.gov/alerts/IR-ALERT-H-16-056-01.*

[8] *Id.* at Mitigation Section. By "strategic technology refresh," the Alert referred to the benefit of replacing legacy cyber systems that no longer receive security patches and, as a result, might not be secure.

[9] Logical ports are connection points where two applications communicate to identify different applications or processes running on a cyber asset.

[10] A physical port serves as an interface or connection between a cyber asset and another cyber asset, or peripheral device, using a physical medium such as a cable.

[11] NERC defines an electronic security perimeter as "the logical border surrounding a network to which BES Cyber Systems are connected using a routable protocol." NERC Glossary at 39.

Internet.[12] Logical separation, in some contexts, can achieve a similar objective through different means.

11. The Commission seeks comment on whether the CIP Reliability Standards should be modified to require isolation between the Internet and BES Cyber Systems in Control Centers performing the functions of a transmission operator. In addition, the Commission seeks comment on the operational impact to the Bulk-Power System if BES Cyber Systems were isolated from the Internet in all Control Centers performing transmission operator functions. Specifically, the Commission seeks comment on what, if any, reliability issues might arise from such a requirement. For example, would requiring isolation prevent an activity required by another Reliability Standard? If isolation is required, is logical isolation preferable to physical isolation (or vice versa) and, if so, why? The Commission also seeks comment on whether and how such a requirement might affect a transmission operator's communications with its reliability coordinator or other applicable entities required under the Reliability Standard. Finally, if isolation is not required, are there communications with these Control Centers for which the use of one-way data diodes would be reliable and appropriate?

B. Application Whitelisting for BES Cyber Systems in Control Centers

12. Application whitelisting is a computer administration practice used to prevent unauthorized programs from running.[13] The purpose is primarily to protect computers and networks from harmful applications, and, to a lesser extent, to prevent unnecessary demand for computer resources. The "whitelist" is a list of applications granted permission to run by the user or an administrator. Whitelisting works best when applied to static cyber systems.[14]

13. In response to the Ukraine incident, the Alert recommended that:

> asset owners take defensive measures by leveraging best practices to minimize the risk from similar malicious cyber activity. Application Whitelisting (AWL) can detect and prevent attempted execution of malware uploaded by malicious actors. The static nature of some systems, such as database servers and HMI computers, make these ideal candidates to run AWL. Operators are encouraged to work with their vendors to baseline and calibrate AWL deployments.

Similarly, a December 2015 document by DHS identifies application whitelisting as the first of seven strategies to defend industrial control systems and states that this strategy would have "potentially mitigated" 38 percent of ICS–CERT Fiscal Year 2014 and 2015 incidents, more than any of the other strategies.[15] While the NERC Guidelines and Technical Basis document associated with Reliability Standard CIP–007–6, Requirement R3 identifies application whitelisting as an option for mitigating malicious cyber activity, its use is not mandatory.[16] The Guidelines and Technical Basis discussion in Reliability Standard CIP–007–6 explains:

> Due to the wide range of equipment comprising the BES Cyber Systems and the wide variety of vulnerability and capability of that equipment to malware as well as the constantly evolving threat and resultant tools and controls, it is not practical within the standard to prescribe how malware is to be addressed on each Cyber Asset. Rather, the Responsible Entity determines on a BES Cyber System basis, which Cyber Assets have susceptibility to malware intrusions and documents their plans and processes for addressing those risks and provides evidence that they follow those plans and processes. There are numerous options available including traditional antivirus solutions for common operating systems, white-listing solutions, network isolation techniques, Intrusion Detection/Prevention (IDS/IPS) solutions, etc.[17]

14. While application whitelisting is identified above as one available option, the Ukraine incident and the subsequent Alert raise the question of whether application whitelisting should be required. Application whitelisting could be a more effective mitigation tool than other mitigation measures because whitelisting allows only software applications and processes that are reviewed and tested before use in the system network. By knowing all installed applications, the security professional can set the application whitelisting program to know the application is approved; all unapproved applications will trigger an alert.

15. The Commission seeks comment on whether the CIP Reliability Standards should be modified to require application whitelisting for all BES Cyber Systems in Control Centers. Is application whitelisting appropriate for all such systems? If not, are there certain devices or components on such systems for which it is appropriate? In addition, the Commission seeks comment on the operational impact, including potential reliability concerns, for each approach.

III. Comment Procedures

16. The Commission invites interested persons to submit comments, and other information on the matters, issues and specific questions identified in this notice. Comments are due September 26, 2016. Comments must refer to Docket No. RM16–18–000, and must include the commenter's name, the organization they represent, if applicable, and their address in their comments.

17. The Commission encourages comments to be filed electronically via the eFiling link on the Commission's Web site at *http://www.ferc.gov.* The Commission accepts most standard word processing formats. Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format. Commenters filing electronically do not need to make a paper filing.

18. Commenters that are not able to file comments electronically must send an original of their comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

19. All comments will be placed in the Commission's public files and may be viewed, printed, or downloaded remotely as described in the Document Availability section below. Commenters on this proposal are not required to serve copies of their comments on other commenters.

IV. Document Availability

20. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through FERC's Home Page (*http://www.ferc.gov*) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE., Room 2A, Washington, DC 20426.

21. From FERC's Home Page on the Internet, this information is available on

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[12] *See* Alert at Mitigation Section; *see also* Department of Homeland Security, *Seven Steps to Effectively Defend Industrial Control Systems* at 3.

[13] *See* Alert at Mitigation Section.

[14] *Id.*

[15] Seven Steps to Effectively Defend Industrial Control Systems at 1.

[16] Reliability Standard CIP–007–6, Requirement R3 provides that "[e]ach Responsible Entity shall implement one or more documented process(es) that collectively include each of the applicable requirement parts in CIP–007–6 Table R3—Malicious Code Prevention" and lists application whitelisting as an option. In addition, the CIP Reliability Standards require a combination of ensuring that an individual's privileges are the minimum necessary to perform their work function (*i.e.,* "least privilege") and anti-malware (*i.e.,* "blacklisting"). *See, e.g.,* Reliability Standard CIP–004–6, Requirement R4 and Guidelines and Technical Basis; Reliability Standard CIP–007–6, Requirement R3.

[17] Reliability Standard CIP–007–6, Guidelines and Technical Basis, at 4.

eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

22. User assistance is available for eLibrary and the FERC's Web site during normal business hours from FERC Online Support at 202–502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

By direction of the Commission.

Issued: July 21, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–17854 Filed 7–27–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. EL16–101–000]

Tri-State Generation and Transmission Association, Inc.; Notice of Petition for Partial Waiver

July 20, 2016.

Take notice that on July 15, 2016, pursuant to section 292.402 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure,[1] Tri-State Generation and Transmission Association, Inc. (Tri-State) on behalf of itself and its electric distribution cooperative member-owners (collectively, the Participating Members),[2] filed a petition for partial waiver of certain obligations imposed on Tri-State and the Participating Members under Sections 292.303(a) and 292.303(b) of the Commission's regulations, all as more fully explained in the petition.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible online at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern time on August 5, 2016.

Dated: July 20, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–17858 Filed 7–27–16; 8:45 am]

BILLING CODE 6717–01–P

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[1] 18 CFR 292.402.

[2] Tri-State's member owners joining in this petition are Big Horn Rural Electric Company, Carbon Power and Light, Inc., Central New Mexico Electric Cooperative, Inc., Chimney Rock Public Power District, Continental Divide Electric Cooperative, Inc., Garland Light and Power Company, High Plains Power, Inc., High West Energy, Inc., Highline Electric Association, Jemez Mountains Electric Cooperative, Inc., K.C. Electric Association, Inc., The Midwest Electric Cooperative Corporation, Mora-San Miguel Electric Cooperative, Inc., Morgan County Rural Electric Association, Mountain Parks Electric, Inc., Mountain View Electric Association, Inc., Niobrara Electric Association, Inc., Northern Rio Arriba Electric Cooperative, Inc., Otero County Electric Cooperative, Inc., Panhandle Rural Electric Membership Association, Roosevelt Public Power District, San Luis Valley Rural Electric Cooperative, Inc., Sierra Electric Cooperative, Inc., Socorro Electric Cooperative, Inc., Southeast Colorado Power Association, Southwestern Electric Cooperative, Inc., Springer Electric Cooperative, Inc., Wheatland Rural Electric Association, Inc., Wyrulec Company, and Y–W Electric Association, Inc.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14680–002]

Water Street Land, LLC; Notice of Application Tendered for Filing With the Commission and Soliciting Additional Study Requests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Exemption from Licensing.

b. *Project No.:* 14680–002.

c. *Date filed:* July 13, 2016.

d. *Applicant:* Water Street Land, LLC.

e. *Name of Project:* Natick Pond Dam Hydroelectric Project.

f. *Location:* On the Pawtuxet River, in the Towns of Warwick and West Warwick, in Kent County, Rhode Island. No federal lands would be occupied by project works or located within the project boundary.

g. *Filed Pursuant to:* Public Utility Regulatory Policies Act of 1978, 16 U.S.C. 2705, 2708 (2012), *amended by* the Hydropower Regulatory Efficiency Act of 2013, Pub. L. 113–23, 127 Stat. 493 (2013).

h. *Applicant Contact:* Mr. Rob Cioe, Water Street Land, LLC, P.O. Box 358, North Kingstown, Rhode Island 02852; (480) 797–3077.

i. *FERC Contact:* John Ramer, (202) 502–8969, *john.ramer@ferc.gov.*

j. *Cooperating agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item l below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See,* 94 FERC ¶ 61,076 (2001).

k. Pursuant to section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.

l. Deadline for filing additional study requests and requests for cooperating agency status: September 12, 2016.

The Commission strongly encourages electronic filing. Please file additional study requests and requests for cooperating agency status using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–14680–002.

m. The application is not ready for environmental analysis at this time.

n. The proposed Natick Pond Dam Project would consist of: (1) An existing 265-foot-long granite block dam with a 166-foot-long spillway; (2) an existing 58-foot to 125.3-foot-wide, 1-foot to 28-foot-deep earth embankment; (3) an existing 44-foot-long, 4-foot to 20-foot-high south granite block training wall; (4) an existing 1,244-foot-long, 18-foot to 41.25-foot-high granite block and cobble stone north training wall; (5) an existing 4-foot-wide, 6-foot-high granite block low level outlet; (6) an existing 46.0-acre impoundment (Natick Pond) with a normal surface elevation of about 48.5 feet North American Vertical Datum of 1988; (7) a new 97-foot-long, 32.2-foot-wide, 6.6-foot-deep concrete intake channel; (8) a new 7.6-foot-high, 11.1-foot-wide steel sluice gate with a new 8.3-foot-high, 32.2-foot-wide steel trashrack with 6-inch clear bar spacing; (9) two new 113-foot-long, 28-foot-wide concrete turbine bays containing two 42.7-foot-long, 9.2-foot-diameter Archimedes screw turbine-generator units each rated at 180 kilowatts (kW) for a total installed capacity of 360 kW; (10) a new 20.8-foot-high, 23.8-foot-long, 27.8-foot-wide concrete powerhouse containing a new gearbox and electrical controls; (11) a new 43-foot long, 29-foot-wide, 5-foot-deep tailrace; (12) a new 220-foot-long, 12.47-kilovolt above-ground transmission line connecting the powerhouse to National Grid's distribution system; and (13) appurtenant facilities. The estimated annual generation of the proposed Natick Pond Dam Project would be about 1,800 megawatt-hours. The applicant proposes to operate the project in a run-of-river mode. There are no federal or state lands associated with the project.

o. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support. A copy is also available for inspection and reproduction at the address in item h above.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

p. With this notice, we are initiating consultation with the Rhode Island State Historic Preservation Officer (SHPO), as required by section 106 of the National Historic Preservation Act and the regulations of the Advisory Council on Historic Preservation, 36 CFR 800.4.

q. *Procedural schedule:* The application will be processed according to the following preliminary schedule. Revisions to the schedule will be made as appropriate (*e.g.,* study requests and/or application deficiencies may lengthen the schedule).

Issue Deficiency Letter	August 2016
Issue Notice of Acceptance/ Ready for Environmental Analysis	October 2016
Issue EA/Order	January 2017

Dated: July 20, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–17849 Filed 7–27–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER16–1546–001.

Applicants: Southwest Power Pool, Inc.

Description: Tariff Amendment: Deficiency Response in ER16–1546—Arkansas Electric Coop. Corp. Formula Rate to be effective 7/1/2016.

Filed Date: 7/21/16.

Accession Number: 20160721–5088.

Comments Due: 5 p.m. ET 8/11/16.

Docket Numbers: ER16–2261–000.

Applicants: The Connecticut Light and Power Company.

Description: Section 205(d) Rate Filing: PSEG Power CT Engineering Design Siting-Original Service Agreement No. IA–ES–35 to be effective 7/5/2016.

Filed Date: 7/21/16.

Accession Number: 20160721–5068.

Comments Due: 5 p.m. ET 8/11/16.

Docket Numbers: ER16–2262–000.

Applicants: Public Service Company of Colorado.

Description: Section 205(d) Rate Filing: PSCo CSU CO&M JF SS Agrmt 395 0.0.0 to be effective 9/20/2016.

Filed Date: 7/21/16.

Accession Number: 20160721–5075.

Comments Due: 5 p.m. ET 8/11/16.

Docket Numbers: ER16–2263–000.

Applicants: Telysium Energy Marketing, LLC.

Description: Baseline eTariff Filing: Telysium Energy Marketing, LLC Market-Based Rate Tariff to be effective 7/30/2016.

Filed Date: 7/21/16.

Accession Number: 20160721–5087.

Comments Due: 5 p.m. ET 8/11/16.

Docket Numbers: ER16–2264–000.

Applicants: Tampa Electric Company.

Description: Compliance filing: Compliance Filing Under Order 827 to be effective 9/21/2016.

Filed Date: 7/21/16.

Accession Number: 20160721–5090.

Comments Due: 5 p.m. ET 8/11/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 21, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–17835 Filed 7–27–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Commissioner and Staff Attendance at the National Association of Regulatory Utility Commissioners Summer Committee Meetings

The Federal Energy Regulatory Commission (Commission) hereby gives notice that members of the Commission and/or Commission staff may attend the 2016 National Association of Regulatory Utility Commissioners Summer Committee Meetings, including the following:

General Session—July 25, 2016, 8:30 a.m.–10:30 a.m. (CDT)
Committee on Electricity Meeting—July 25, 2016, 10:45 a.m.–5 p.m. (CDT)
Committee on Electricity Meeting—July 26, 2016, 10:45 a.m.–5:15 p.m. (CDT)

The above-referenced meetings will be held at: Omni Nashville Hotel, 250 Fifth Avenue South, Nashville, TN 37203.

Further information may be found at *http://naruc.org/summermeetings/.*

The discussions at the meetings described above may address matters at issue in the following proceedings:

Docket No. ER10–1453, *FirstEnergy Generation Mansfield Unit 1 Corp.*
Docket No. ER10–1459, *FirstEnergy Solutions Corp.*
Docket No. ER10–1467, *Ohio Edison Company*
Docket No. ER10–1468, *Toledo Edison Company*
Docket No. ER10–1469, *Cleveland Electric Illuminating Company*
Docket No. ER13–713, *FirstEnergy Nuclear Generation, LLC*
Docket No. ER13–785, *FirstEnergy Generation, LLC*
Docket No. ER13–1874, *American Electric Power Service Corporation*
Docket No. ER13–1896, *AEP Generation Resources Inc.*
Docket No. ER14–95, *American Electric Power Service Corporation*
Docket No. ER14–594, *Ohio Power Company*
Docket No. ER14–1639, *ISO New England Inc.*
Docket No. ER16–120, *New York Independent System Operator, Inc.*
Docket No. ER16–1404, *New York Independent System Operator, Inc.*
Docket No. ER16–1649, *California Independent System Operator Corporation*
Docket No. ER16–1807, *FirstEnergy Solutions Corp.*
Docket No. EL13–62, *Independent Power Producers of New York, Inc.,* v. *New York Independent System Operator, Inc.*
Docket No. EL16–49, *Calpine Corporation, et al.* v. *PJM Interconnection, L.L.C.*
Docket No. EL16–93, *NextEra Energy Resources, LLC and PSEG Companies* v. *ISO New England Inc.*

For more information, contact Sandra Waldstein, Office of External Affairs, Federal Energy Regulatory Commission at (202) 502–8092 or *sandra.waldstein@ferc.gov.*

Dated: July 22, 2016.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

[FR Doc. 2016–17878 Filed 7–27–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP16–1097–000.
Applicants: KO Transmission Company.
Description: Section 4(d) Rate Filing: KO Transmission Rate Case Filing to be effective 2/1/2017.
Filed Date: 7/14/16.
Accession Number: 20160714–5174.
Comments Due: 5 p.m. ET 7/26/16.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: CP16–26–001.
Applicants: MoGas Pipeline LLC.
Description: MoGas Pipeline LLC's Compliance Filing as Directed by Order Approving Abandonment and Accounting Procedures for Consolidated/Combined Accounting Procedures under CP16–26.
Filed Date: 6/30/16.
Accession Number: 20160630–5060.
Comments Due: 5 p.m. ET 7/26/16.

Any person desiring to protest in any of the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 20, 2016.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

[FR Doc. 2016–17840 Filed 7–27–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER16–2240–000]

Rush Springs Wind Energy, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Rush Springs Wind Energy, LLC‘s application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 10, 2016.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 21, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–17837 Filed 7–27–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER16–2241–000]

Ninnescah Wind Energy, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Ninnescah Wind Energy, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 10, 2016.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 21, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–17838 Filed 7–27–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 4254–011]

Brentwood Dam Ventures, LLC; Notice of Proposed Termination of Exemption by Implied Surrender and Soliciting Comments, Protests and Motions To Intervene

Take notice that the following hydroelectric proceeding has been initiated by the Commission:

a. *Type of Proceeding:* Proposed Termination of Exemption by Implied Surrender.

b. *Project No.:* 4254–011.

c. *Date Initiated:* July 20, 2016.

d. *Exemptee:* Brentwood Dam Ventures, LLC.

e. *Name and Location of Project:* Exeter River Hydro #1 Project located on the Exeter River, in Rockingham County, New Hampshire.

f. *Filed Pursuant to:* 18 CFR 4.106.

g. *Exemptee Contact Information:* Mr. Naoto Inoue, 25 Limerick Road, Arundel, Maine 04046, Phone: (207) 985–0088.

h. *FERC Contact:* Mr. Ashish Desai, (202) 502–8370, *Ashish.Desai@ferc.gov.*

i. Deadline for filing comments, protests, and motions to intervene is 30 days from the issuance date of this notice by the Commission. The Commission strongly encourages electronic filing. Please file comments, protests, and motions to intervene using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–4254–011.

j. *Description of Project Facilities:* (1) An 110-foot-long, 15-foot-high concrete dam; (2) a 24-acre reservoir; (3) an intake structure; (4) turbine-generator units with an installed capacity of 72 kilowatts; and (5) appurtenant facilities.

k. *Description of Proceeding:* The exemptee is in violation of Standard Article 1 of the exemption, issued on December 1, 1981 (17 FERC ¶ 62,321), and the Commission's regulations at 18 CFR 4.106. Article 1 provides, among other things, that the Commission reserves the right to revoke an exemption if any term or condition of the exemption is violated.

The exemptee's failure to operate and maintain the project as authorized by its exemption is a violation of Standard Article 1. Commission records indicate that the project has not been operated since 1998. The current exemptee acquired the project in February 2009 and has been unable to restore project operation. On December 19, 2013, the exemptee filed a plan and schedule to restore project operation, which Commission staff approved with the requirement that the exemptee file quarterly progress reports starting October 1, 2014. The exemptee did not file the first progress report. By letter on December 19, 2014, Commission staff requested that the exemptee file the overdue progress report. In response, on January 9, 2015, the exemptee filed a request for an extension of time stating it was unable to move forward with the approved plan and schedule and needed more time to reevaluate and formulate a plan of action. By telephone on March 12, 2015, Commission staff contacted the exemptee to inquire about the non-operational status of the project. In response, the exemptee reiterated its need for additional time and stated it was looking for a buyer for the project. By letter on April 15, 2016, Commission staff again requested that the exemptee file a plan and schedule to restore project operation. In addition, Commission staff informed the exemptee that it was non-compliant with the exemption and that failure to maintain and operate the project as authorized would result in termination of the exemption by the Commission. On April 27, 2016, the exemptee filed a response stating the project was still for sale, but did not file a plan and schedule or any other information regarding its efforts to restore project operation.

l. This notice is available for review and reproduction at the Commission in the Public Reference Room, Room 2A, 888 First Street NE., Washington, DC 20426. The notice and other project records may also be viewed on the Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the Docket number (P–4254–011) excluding the last three digits in the docket number field to access the notice. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call toll-free (866) 208–3676 or email *FERCOnlineSupport@ferc.gov.* For TTY, call (202) 502–8659.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, and .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents:* Any filing must (1) bear in all capital letters the title "COMMENTS," "PROTEST," or "MOTION TO INTERVENE" as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All comments, protests, or motions to intervene should relate to project works which are the subject of the implied surrender. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: July 20, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–17860 Filed 7–27–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2960–006; ER10–1618–006; ER10–1616–006; ER10–1598–006; ER10–1595–006.

Applicants: Astoria Generating Company, L.P., Crete Energy Venture, LLC, Lincoln Generating Facility, LLC, New Covert Generating Company, LLC, Rolling Hills Generating, L.L.C.

Description: Supplement to May 31, 2016 Notice of Non-Material Change in Status of Astoria Generating Company, L.P., et al.

Filed Date: 7/20/16.

Accession Number: 20160720–5162.

Comments Due: 5 p.m. ET 8/10/16.

Docket Numbers: ER16–1443–000.

Applicants: NRG Power Midwest LP.

Description: Report Filing: Refund Report—Informational Filing to be effective N/A.

Filed Date: 7/20/16.

Accession Number: 20160720–5062.

Comments Due: 5 p.m. ET 8/10/16.

Docket Numbers: ER16–1638–001.

Applicants: 4C Acquisition, LLC.

Description: Tariff Amendment: Response to Request for Additional Information of 4CA to be effective 8/4/2016.

Filed Date: 7/20/16.

Accession Number: 20160720–5131.

Comments Due: 5 p.m. ET 8/10/16.

Docket Numbers: ER16–2252–000.

Applicants: Antelope DSR 1, LLC.

Description: Baseline eTariff Filing: Antelope DSR 1, LLC Co-Tenancy Agreement to be effective 8/1/2016.

Filed Date: 7/20/16.

Accession Number: 20160720–5124.

Comments Due: 5 p.m. ET 8/10/16.

Docket Numbers: ER16–2253–000.

Applicants: Antelope DSR 2, LLC.

Description: Baseline eTariff Filing: Antelope DSR 2, LLC Co-Tenancy Agreement to be effective 8/1/2016.

Filed Date: 7/20/16.

Accession Number: 20160720–5126.

Comments Due: 5 p.m. ET 8/10/16.

Docket Numbers: ER16–2254–000.

Applicants: Antelope DSR 3, LLC.

Description: Baseline eTariff Filing: Antelope DSR 3, LLC Co-Tenancy Agreement to be effective 8/1/2016.

Filed Date: 7/20/16.

Accession Number: 20160720–5127.

Comments Due: 5 p.m. ET 8/10/16.

Docket Numbers: ER16–2255–000.

Applicants: Elevation Solar C LLC.

Description: Baseline eTariff Filing: Elevation Solar C LLC Co-Tenancy Agreement to be effective 8/1/2016.

Filed Date: 7/20/16.

Accession Number: 20160720–5128.

Comments Due: 5 p.m. ET 8/10/16.

Docket Numbers: ER16–2256–000.

Applicants: Solverde 1, LLC.

Description: Baseline eTariff Filing: Solverde 1, LLC Co-Tenancy Agreement to be effective 8/1/2016.

Filed Date: 7/20/16.

Accession Number: 20160720–5129.

Comments Due: 5 p.m. ET 8/10/16.

Docket Numbers: ER16–2257–000.

Applicants: Western Antelope Blue Sky Ranch B LLC.

Description: Baseline eTariff Filing: Western Antelope Blue Sky Ranch B LLC Co-Tenancy Agreement to be effective 8/1/2016.

Filed Date: 7/20/16.

Accession Number: 20160720–5130.

Comments Due: 5 p.m. ET 8/10/16.

Docket Numbers: ER16–2258–000.
Applicants: Southwest Power Pool, Inc.
Description: Section 205(d) Rate Filing: Gas-Electric Coordination Provisions Clean-Up and Effective Date Change to be effective 9/30/2016.
Filed Date: 7/20/16.
Accession Number: 20160720–5132.
Comments Due: 5 p.m. ET 8/1/16.

Docket Numbers: ER16–2259–000.
Applicants: WSPP Inc.
Description: Section 205(d) Rate Filing: Normal filing Schedule Q 2016 to be effective 8/3/2016.
Filed Date: 7/21/16.
Accession Number: 20160721–5015.
Comments Due: 5 p.m. ET 8/11/16.

Docket Numbers: ER16–2260–000.
Applicants: PJM Interconnection, L.L.C., American Municipal Power, Inc., Duke Energy Ohio, Inc.
Description: Section 205(d) Rate Filing: Revised Service Agreement No. 4264—NITSA between PJM and AMP to be effective 1/1/2016.
Filed Date: 7/21/16.
Accession Number: 20160721–5041.
Comments Due: 5 p.m. ET 8/11/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 21, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–17834 Filed 7–27–16; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9949–83–Region 4]

Public Water System Supervision Program Revision for the State of Florida

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of tentative approval.

SUMMARY: Notice is hereby given that the State of Florida is revising its approved Public Water System Supervision Program. Florida has adopted the following rules: Stage 2 Disinfectants and Disinfection Byproducts Rule, Long Term 2 Enhanced Surface Water Treatment Rule, and Ground Water Rule. The Environmental Protection Agency (EPA) has determined that Florida's rules are no less stringent than the corresponding federal regulations. Therefore, EPA is tentatively approving this revision to the State of Florida's Public Water System Supervision Program.

DATES: Any interested person may request a public hearing. A request for a public hearing must be submitted by August 29, 2016, to the Regional Administrator at the EPA Region 4 address shown below. The Regional Administrator may deny frivolous or insubstantial requests for a hearing. However, if a substantial request for a public hearing is made by August 29, 2016, a public hearing will be held. If no timely and appropriate request for a hearing is received and the Regional Administrator does not elect to hold a hearing on her own motion, this tentative approval shall become final and effective on August 29, 2016. Any request for a public hearing shall include the following information: The name, address, and telephone number of the individual, organization, or other entity requesting a hearing; a brief statement of the requesting person's interest in the Regional Administrator's determination and a brief statement of the information that the requesting person intends to submit at such hearing; and the signature of the individual making the request, or, if the request is made on behalf of an organization or other entity, the signature of a responsible official of the organization or other entity.

ADDRESSES: All documents relating to this determination are available for inspection between the hours of 8:30 a.m. and 4:30 p.m., Monday through Friday, at the following offices: Florida Department of Environmental Protection, Drinking Water and Aquifer Protection Program, 2600 Blair Stone Road, Tallahassee, Florida 32399; and the U.S. Environmental Protection Agency, Region 4, Drinking Water Section, 61 Forsyth Street SW., Atlanta, Georgia 30303.

FOR FURTHER INFORMATION CONTACT: Dale Froneberger, EPA Region 4, Drinking Water Section, by mail at the Atlanta address given above, by telephone at (404) 562–9446, or by email at *froneberger.dale@epa.gov.*

SUPPLEMENTARY INFORMATION: On March 20, 2013, the State of Florida submitted requests that EPA Region 4 approve a revision to the State's Safe Drinking Water Act Public Water System Supervision Program to include the authority to implement and enforce the Stage 2 Disinfectants and Disinfection Byproducts Rule, the Long Term 2 Enhanced Surface Water Treatment Rule, and the Ground Water Rule. For the requests to be approved, EPA must find the state rules codified at Chapters 62–550 and 62–560, F.A.C., to be no less stringent than the federal rules codified at 40 CFR part 141, subpart A—General; 40 CFR part 141, subpart C—Monitoring and Analytical Requirements; 40 CFR part 141, subpart D—Reporting and Recordkeeping; 40 CFR part 141, subpart G—Maximum Contaminant Levels and Maximum Residual Disinfectant Levels; 40 CFR part 141, subpart L—Disinfectant Residuals, Disinfection Byproducts, and Disinfection Byproduct Precursors; 40 CFR part 141, subpart O—Consumer Confidence Reports; 40 CFR part 141, subpart Q—Public Notification of Drinking Water Violations; 40 CFR part 141, subpart S—Ground Water Rule; 40 CFR part 141, subpart U—Initial Distribution System Evaluations; 40 CFR part 141, subpart V—Stage 2 Disinfection Byproducts Requirements; and 40 CFR part 141, subpart W—Enhanced Treatment for *Cryptosporidium*. EPA reviewed the applications using the federal statutory provisions (Section 1413 of the Safe Drinking Water Act), federal regulations (at 40 CFR part 142), state regulations, rule crosswalks, and EPA regulatory guidance to determine whether the requests for revision are approvable. EPA determined that the Florida regulations are no less stringent than the corresponding federal regulations and is tentatively approving this revision. If EPA does not receive a timely and appropriate request for a hearing and the Regional Administrator does not elect to hold a hearing on her own motion, this approval will become final and effective on August 29, 2016.

Authority: Section 1413 of the Safe Drinking Water Act, as amended (1996), and 40 CFR part 142.

Dated: June 1, 2016.

Heather McTeer Toney,

Regional Administrator, Region 4.

[FR Doc. 2016–17898 Filed 7–27–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL 9949–59–Region 6; Permit NMG010000]

Final National Pollutant Discharge Elimination System General Permit for Discharges From Concentrated Animal Feeding Operations in New Mexico

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final NPDES general permit issuance.

SUMMARY: The Director of the Water Quality Division, EPA Region 6, provides notice of reissuance of the National Pollutant Discharge Elimination System (NPDES) General Permit No. NMG010000 for existing and new dischargers in New Mexico, under the Concentrated Animal Feeding Operations (CAFO) Point Source Category and producing Horses, Dairy Cows, and Cattle other than Veal Calves, except those discharges on Indian Country. A copy of the Region's responses to comments and the final permit may be obtained from the EPA Region 6 Internet site: *http://www.epa.gov/region6/water/npdes/cafo/index.htm.*

DATES: This permit is effective, and is deemed issued for the purpose of judicial review, on September 1, 2016, and expires August 31, 2021. Under section 509(b) of the CWA, judicial review of this general permit can be held by filing a petition for review in the United States Court of Appeals within 120 days after the permit is considered issued for judicial review. Under section 509(b)(2) of the CWA, the requirements in this permit may not be challenged later in civil or criminal proceedings to enforce these requirements. In addition, this permit may not be challenged in other agency proceedings.

FOR FURTHER INFORMATION CONTACT: Ms. Evelyn Rosborough, Region 6, U.S. Environmental Protection Agency, 1445 Ross Avenue, Dallas, Texas 75202–2733. Telephone: (214) 665–7515.

SUPPLEMENTARY INFORMATION:

Summary of Significant Changes From the Draft Permit

Pursuant to section 402 of the Clean Water Act (CWA), 33 U.S.C. 1342, EPA proposed and solicited comments on NPDES general permit NMG010000 at *FRL–9921–07–Region 6* (December 30, 2014). Discharges eligible for coverage under the permit are from animal feeding operations that are defined as CAFOs or designated as CAFOs by the permitting authority and that are subject to 40 CFR part 412, subparts A (Horses) and C (Dairy Cows and Cattle Other than Veal Calves) and that discharge or propose to discharge pollutants to waters of the United States. The public comment period ended March 2, 2015. The State of New Mexico Environmental Department (NMED) received an extension to April 15, 2015, for certified comments. Region 6 received comments from the New Mexico Environment Department, New Mexico Farm & Livestock Bureau, New Mexico Department of Agriculture, Texas Cattle Feeders Association, Socially Responsible Agriculture Project, the New Mexico Environmental Law Center, Animal Legal Defense Fund, Sierra Club—Rio Grande Chapter, Amigos Bravos, Lea County Concerned Citizens, Rio Valle Concerned Citizens, and Mesquite Community Action Committee, Enviro Compliance Services, Inc., and Erika Brotzman. EPA Region 6 has considered all comments received. In response to those comments the following significant changes are made to the proposed permit. All changes are discussed in the response to comments documents.

1. Permit Part II.A.5.a.ii. is revised to require calibration of land application equipment to be performed at least annually, in accordance with procedures and schedules to be established in the nutrient management plan for all equipment.

2. Permit Part I.E.8. is updated to require Notice of Intent (NOI) and Nutrient Management Plan (NMP) submittals to NMED.

3. Permit Part I.H, Change in Ownership is clarified and Permit Part I. E.9. is revised to remove the 7 day public review and comment for NOIs resulting from transfer of ownership of a facility with prior permit coverage.

4. Permit Part II.A.2.a.v. is clarified regarding equipment inspection deficiencies to specify deficiencies not corrected in 30 days to be explained.

5. Permit Part III. B. is revised to align facility closure requirements with New Mexico impoundment closure requirements.

6. Permit Part III.C.1.b. is changed to require retention of the telephone number of the recipient of any transferred manure, litter or process wastewater.

7. Permit Part V.A. is revised to change the annual report due date from January 31 to March 31.

8. Other minor changes and clarifications.

Other Legal Requirements

A. State Certification

Under section 401(a)(1) of the CWA, EPA may not issue a NPDES permit until the State or Tribal authority in which the discharge will occur grants or waives certification to ensure compliance with appropriate requirements of the CWA and State law. The New Mexico Environment Department issued the 401 certification on April 15, 2015.

B. Other Regulatory Requirements

The Endangered Species Act (ESA) of 1973 requires Federal Agencies such as EPA to ensure, in consultation with the U.S. Fish and Wildlife Service (USFWS) and the National Marine Fisheries Service (NMFS) (also known collectively as the "Services"), that any actions authorized, funded, or carried out by the Agency (*e.g.,* EPA issued NPDES permits authorizing discharges to waters of the United States) are not likely to jeopardize the continued existence of any Federally-listed endangered or threatened species or adversely modify or destroy critical habitat of such species (see 16 U.S.C. 1536(a)(2), 50 CFR part 402 and 40 CFR 122.49(c)). Today's permit is consistent with the ESA section 7(a)(2) consultation between EPA-Region 6 and the USFWS—Albuquerque Field Office, concluded on November 17, 2015.

Authority: Clean Water Act, *33 U.S.C. 1251 et seq.*

Dated: July 14, 2016.

William K. Honker,

Director, Water Division, EPA Region 6.

[FR Doc. 2016–17709 Filed 7–27–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9949–78–OLEM]

The Hazardous Waste Electronic Manifest System Advisory Board: Request for Nominations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Request for nominations.

SUMMARY: The U.S. Environmental Protection Agency (EPA) invites nominations of qualified candidates to be considered for a three-year appointment to fill one IT expert position on the Hazardous Waste Electronic Manifest System Advisory Board (the "Board"). Pursuant to the Hazardous Waste Electronic Manifest Establishment Act (the "e-Manifest Act"

or the "Act"), EPA has established the Board to provide practical and independent advice, consultation, and recommendations to the EPA Administrator on the activities, functions, policies and regulations associated with the Hazardous Waste Electronic Manifest (e-Manifest) System.

DATES: Nominations should be received on or before August 29, 2016.

ADDRESSES: Nominations should be submitted via email to *eManifest@epa.gov,* and identified with "BOARD NOMINATION" in the subject line of the email.

FOR FURTHER INFORMATION CONTACT: Fred Jenkins, Designated Federal Officer (DFO), U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, (MC: 5303P), 1200 Pennsylvania Avenue NW., Washington, DC, 20460, Phone: 703–308–7049; or by email: *jenkins.fred@epa.gov.*

SUPPLEMENTARY INFORMATION: The e-Manifest Act was signed into law on October 5, 2012 (*http://www.gpo.gov/fdsys/pkg/BILLS-112s710enr/pdf/BILLS-112s710enr.pdf*). Under the terms of the e-Manifest Act, 42 U.S.C. 6939(g), EPA is required to establish a national electronic Information Technology (IT) manifest system. This system is to enable users of the uniform hazardous waste manifest forms (EPA Form 8700–22 and Continuation Sheet 8700–22A) to have the option to more efficiently track their hazardous waste shipments electronically, in lieu of the paper manifest, from the point of generation, during transportation, and to the point of receipt by an off-site facility that is permitted to treat, store, recycle, or dispose of the hazardous waste. Electronic manifests obtained from the national system will augment or replace the paper forms that are currently used for this purpose, and that result in substantial paperwork costs and other inefficiencies. Congress intended that EPA develop a system that, among other things, meets the needs of the user community and decreases the administrative burden associated with the current paper-based manifest system on the user community. The Agency anticipates that utilizing electronic manifests will the reduce burden by reporting facilities by 300,000 to 700,000 hours annually, and will produce annualized and discounted cost savings over the initial six years of about $34 million. Undiscounted cost savings should reach $75 million or more each year, once the system is fully established and deployment costs have been paid off. To ensure that these goals are met, the Act directs EPA to establish the Board to assess the effectiveness of the electronic manifest system and make recommendations to the Administrator for improving the system.

In addition, the e-Manifest Act directs EPA to develop a system that attracts sufficient user participation and service revenues to ensure the viability of the system. As a result, the Act provides EPA broad discretion to establish reasonable user fees, as the Administrator determines are necessary, to pay costs incurred in developing, operating, maintaining, and upgrading the system, including any costs incurred in collecting and processing data from any paper manifest submitted to the system after the system enters operation. The Board will meet to assess the adequacy and reasonableness of the service fees and, if necessary, make recommendations to the Administrator to adjust the fees accordingly.

Prior to system deployment, the Board will be asked to provide recommendations on important system development matters and on potential increases or decreases to the amount of a service fee determined under the fee structure. Substantial system development planning work is underway. The Agency is utilizing lean start-up product development strategies with agile, user-centered design and development methodologies, and is currently conducting additional system development procurement activities. The Agency anticipates the initial system deployment to occur in 2018.

The system will provide the functionality of the current paper manifest process, in a more efficient electronic workflow, and will meet all requirements specified in the e-Manifest Act and e-Manifest Final Rule, which was published on February 7, 2014 (*https://www3.epa.gov/epawaste/laws-regs/state/revision/frs/fr231.pdf*). The initial system is envisioned to be a national, electronic system (internet-based) that will enable current users of the manifest form to sign, transmit, archive, and retrieve manifests electronically. The e-Manifest system is further envisioned to allow a fully electronic mobile workflow. The mobile workflow will provide both on-line and off-line capabilities which could enable users to complete an electronic manifest even when internet access is unavailable. EPA envisions that the system will provide all data processing (paper and electronic formats), data storage, and data reporting back out to industry and state users, as well as appropriate public accessibility of data. Finally, e-Manifest aligns with the Agency's E-Enterprise business strategy. E-Enterprise for the Environment is a transformative 21st century strategy—jointly governed by states and EPA—for modernizing government agencies' delivery of environmental protection. Under this strategy, the Agency will streamline its business processes and systems to reduce reporting burden on states and regulated facilities, and improve the effectiveness and efficiency of regulatory programs for EPA, states and tribes.

Although the system has not been completed, the Board is established in accordance with the provisions of the, e-Manifest Act and the Federal Advisory Committee Act (FACA), 5 U.S.C. App.2. The Board is in the public interest and supports EPA in performing its duties and responsibilities. Pursuant to the e-Manifest Act, the Board will be comprised of nine members, of which one member is the Administrator (or a designee), who will serve as Chairperson of the Board, and eight members will be individuals appointed by the EPA administrator:

—At least two of whom have expertise in information technology (IT);
—At least three of whom have experience in using, or represent users of, the manifest system to track the transportation of hazardous waste under federal and state manifest programs; and
—At least three state representatives responsible for processing those manifests.

The Board will meet at least annually as required by the e-Manifest Act. However, additional meetings may occur approximately once every six months or as needed and approved by the DFO.

Member Nominations: Pursuant to the e-Manifest Act, the Board will assist the Agency in evaluating the effectiveness of the e-Manifest IT system and associated user fees; identifying key issues associated with the system, including the need (and timing) for user fee adjustments; system enhancements; and providing independent advice on matters and policies related to the e-Manifest program. The Board will provide recommendations on matters related to the operational activities, functions, policies, and regulations of EPA under the e-Manifest Act, including proposing actions to encourage the use of the electronic (paperless) system, and actions related to the E-Enterprise strategy that intersect with e-Manifest. These intersections may include issues such as business to business communications, performance standards for mobile devices, and Cross Media Electronic Reporting Rule (CROMERR) compliant e-signatures.

Any interested person and/or organization may nominate qualified individuals for membership. EPA values and welcomes diversity. In an effort to obtain nominations of diverse candidates, the Agency encourages nominations of women and men of all racial and ethnic groups. All candidates will be considered and screened against the criteria listed below as well as EPA's Conflict of Interest (COI) and appearance of bias guidance (*http://www.epa.gov/peerreview/pdfs/spc_peer_rvw_handbook_addendum.pdf* and *http://www.epa.gov/osa/pdfs/epa-process-for-contractor.pdf*). Currently there is one IT expert position available to be filled on the Board. The other positions have already been filled pursuant to EPA's request for nominations that was previously published in the **Federal Register** (80 FR 8643, February 18, 2015).

IT nominees should have core competencies and experience in large scale systems and application development and integration, deployment and maintenance, user help desk and support, and expertise relevant to support the complexity of an e-Manifest system. Examples of this expertise may include but are not limited to: Expertise with web-based and mobile technologies, particularly that support large scale operations for geographically diverse users; expertise in IT security, including perspective on federal IT security requirements; expertise in electronic signature and user management approaches; expertise with scalable hosting solutions such as cloud-based hosting; and expertise in user experience. Existing knowledge of, or willingness to gain an understanding of EPA shared services and enterprise architecture is a plus as is experience in setting and managing fee-based systems in general. Additional criteria used to evaluate nominees include:

- Excellent interpersonal, oral, and written communication skills;
- Demonstrated experience developing group recommendations;
- Willingness to commit time to the Board and demonstrated ability to work constructively on committees;
- Absence of financial conflicts of interest;
- Impartiality (including the appearance of impartiality); and
- Background and experiences that would help members contribute to the diversity of perspectives on the Board, *e.g.*, geographic, economic, social, cultural, educational backgrounds, professional affiliations, and other considerations.

Nominations must include a resume, which provides the nominee's background, experience and educational qualifications, as well as a brief statement (one page or less) describing the nominee's interest in serving on the Board and addressing the other criteria previously described. Nominees are encouraged to provide any additional information that they believe would be useful for consideration, such as: Availability to participate as a member of the Board; how the nominee's background, skills and experience would contribute to the diversity of the Board; and any concerns the nominee has regarding membership. Nominees should be identified by name, occupation, position, current business address, email, and telephone number. Interested candidates may self-nominate. The Agency will acknowledge receipt of nominations.

The person selected for membership will receive compensation for travel and a nominal daily compensation (if appropriate) while attending meetings. Additionally, the selected candidate will be designated as a Special Government Employee (SGE) or consultant. Candidates designated as SGEs are required to fill out the "Confidential Financial Disclosure Form for Environmental Protection Agency Special Government Employees" (EPA Form 3310–48). This confidential form provides information to EPA ethics officials to determine whether there is a conflict between the SGE's public duties and their private interests, including an appearance of a loss of impartiality as defined by federal laws and regulations. One example of a potential conflict of interest may be for IT professional(s) serving in an organization that is awarded any related e-Manifest system development contract(s).

Dated: July 15, 2016.

Barnes Johnson,

Director, Office of Resource Conservation and Recovery, Office of Land and Emergency Management.

[FR Doc. 2016–17782 Filed 7–27–16; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (*www.fmc.gov*) or by contacting the Office of Agreements at (202)-523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 012427.

Title: CMA CGM/APL Panama—USWC Space Charter Agreement.

Parties: CMA CGM, S.A.; APL Co. Pte Ltd; and American President Lines, Ltd.

Filing Party: Draughn B. Arbona, Esq; CMA CGM (America) LLC; 5701 Lake Wright Drive; Norfolk, VA 23502.

Synopsis: The agreement authorizes APL to charter space to CMA CGM in the trade between Panama and the U.S. West Coast.

Agreement No.: 012428.

Title: CMA CGM/ELJSA Asia—USEC Service Space Charter Agreement.

Parties: CMA CGM S.A. and ELJSA Line Joint Service Agreement.

Filing Party: Paul M. Keane, Esq.; Cichanowicz, Callan, Keane & DeMay, LLP; 50 Main Street, Suite 1045; White Plains, NY; 10606.

Synopsis: The Agreement authorizes Evergreen to charter space to CMA CGM in the trade between Asia and the U.S. East Coast.

By Order of the Federal Maritime Commission.

Dated: July 22, 2016.

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2016–17803 Filed 7–27–16; 8:45 am]

BILLING CODE 6731–AA–P

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in or To Acquire Companies Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 11, 2016.

A. Federal Reserve Bank of Minneapolis (Jacquelyn K. Brunmeier, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Vermillion Bancshares, Inc.*, Vermillion, Minnesota; retroactive notice to engage, de novo, in extending credit and servicing loans pursuant to section 225.28(b)(1) of Regulation Y.

Board of Governors of the Federal Reserve System, July 22, 2016.

Margaret McCloskey Shanks,

Deputy Secretary of the Board.

[FR Doc. 2016–17768 Filed 7–27–16; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System

ACTION: Notice for comment regarding the Federal Reserve proposal to extend, with revision, the clearance under the Paperwork Reduction Act for the following information collection activity.

SUMMARY: The Board of Governors of the Federal Reserve System (Board or Federal Reserve) invites comment on a proposal to extend for three years, with revision, the Capital Assessments and Stress Testing information collection applicable to bank holding companies (BHCs) with total consolidated assets of $50 billion or more and U.S. intermediate holding companies (IHCs) established by foreign banking organizations under 12 CFR 252.153 (FR Y–14A/Q/M; OMB No. 7100–0341).

On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board of Governors of the Federal Reserve System (Board) its approval authority under the Paperwork Reduction Act (PRA), to approve of and assign OMB numbers to collection of information requests and requirements conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the PRA Submission, supporting statements and approved collection of information instruments are placed into OMB's public docket files. The Federal Reserve may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB number.

DATES: Comments must be submitted on or before September 26, 2016.

ADDRESSES: You may submit comments, identified by *FR Y–14A/Q/M*, by any of the following methods:

- *Agency Web site: http://www.federalreserve.gov.* Follow the instructions for submitting comments at *http://www.federalreserve.gov/apps/foia/proposedregs.aspx* .
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: regs.comments@federalreserve.gov.* Include OMB number in the subject line of the message.
- *FAX:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Robert deV. Frierson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW., Washington, DC 20551.

All public comments are available from the Board's Web site at *http://www.federalreserve.gov/apps/foia/proposedregs.aspx* as submitted, unless modified for technical reasons. Accordingly, your comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper form in Room 3515, 1801 K Street (between 18th and 19th Streets NW.) Washington, DC 20006 between 9:00 a.m. and 5:00 p.m. on weekdays.

Additionally, commenters may send a copy of their comments to the OMB Desk Officer, Shagufta Ahmed, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235 725 17th Street NW., Washington, DC 20503 or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of the PRA OMB submission, including the proposed reporting form and instructions, supporting statement, and other documentation will be placed into OMB's public docket files, once approved. These documents will also be made available on the Federal Reserve Board's public Web site at: *http://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears below.

Federal Reserve Board Clearance Officer, Nuha Elmaghrabi, Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551 (202) 452–3884. Telecommunications Device for the Deaf (TDD) users may contact (202) 263–4869, Board of Governors of the Federal Reserve System, Washington, DC 20551.

SUPPLEMENTARY INFORMATION:

Request for Comment on Information Collection Proposal

The following information collection, which is being handled under this delegated authority, has received initial Board approval and is hereby published for comment. At the end of the comment period, the proposed information collection, along with an analysis of comments and recommendations received, will be submitted to the Board for final approval under OMB delegated authority. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Federal Reserve's functions; including whether the information has practical utility;

b. The accuracy of the Federal Reserve's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Proposal to approve under OMB delegated authority the extension for three years with revision of the following report:

1. *Report title:* Capital Assessments and Stress Testing information collection.

Agency form number: FR Y–14A/Q/M.

OMB control number: 7100–0341.

Effective Dates: December 31, 2016 and December 31, 2017.

Frequency: Annually, semi-annually, quarterly, and monthly.

Respondents: The respondent panel consists of any top-tier bank holding company (BHC) or intermediate holding company (IHC) that has $50 billion or more in total consolidated assets, as determined based on: (i) The average of the firm's total consolidated assets in the four most recent quarters as reported quarterly on the firm's Consolidated Financial Statements for Bank Holding

Companies (FR Y–9C) (OMB No. 7100–0128); or (ii) the average of the firm's total consolidated assets in the most recent consecutive quarters as reported quarterly on the firm's FR Y–9Cs, if the firm has not filed an FR Y–9C for each of the most recent four quarters. Reporting is required as of the first day of the quarter immediately following the quarter in which it meets this asset threshold, unless otherwise directed by the Board.

Estimated annual reporting hours: FR Y–14A: Summary, 77,454 hours; Macro Scenario, 2,418 hours; Operational Risk, 702 hours; Regulatory Capital Transitions; 897 hours, Regulatory Capital Instruments, 819 hours; Retail Repurchase Exposures, 1,560 hours; Business Plan Changes, 390 hours; and Adjusted capital plan submission, 500 hours. FR Y–14Q: Retail, 2,496 hours; Securities, 2,184 hours; Pre-provision net revenue (PPNR), 110,916 hours; Wholesale, 23,712 hours; Trading, 46,224 hours; Regulatory Capital Transitions, 3,588 hours; Regulatory Capital Instruments, 8,112 hours; Operational risk, 7,800 hours; Mortgage Servicing Rights (MSR) Valuation, 1,728 hours; Supplemental, 624 hours; Retail Fair Value Option/Held for Sale (Retail FVO/HFS), 1,792 hours; Counterparty, 12,192 hours; and Balances, 2,496 hours; FR Y–14M: 1st lien mortgage, 228,660 hours; Home Equity, 197,760 hours; and Credit Card, 153,000 hours. FR Y–14 On-going automation revisions, 18,720 hours. FR Y–14 Attestation implementation, 14,400 hours; and On-going audit and review, 30,720 hours.

Estimated average hours per response: FR Y–14A: Summary, 993 hours; Macro Scenario, 31 hours; Operational Risk, 18 hours; Regulatory Capital Transitions, 23 hours; Regulatory Capital Instruments, 21 hours; Retail Repurchase Exposures, 20 hours; Business Plan Changes, 10 hours and Adjusted capital plan submission, 100 hours. FR Y–14Q: Retail, 16 hours; Securities, 14 hours; PPNR, 711 hours; Wholesale, 152 hours; Trading, 1,926 hours; Regulatory Capital Transitions, 23 hours; Regulatory Capital Instruments, 52 hours; Operational risk, 50 hours; MSR Valuation, 24 hours; Supplemental, 4 hours; Retail FVO/HFS, 16 hours; Counterparty, 508 hours; and Balances, 16 hours; FR Y–14M: 1st Lien Mortgage, 515 hours; Home Equity, 515 hours; and Credit Card, 510 hours. FR Y–14 On-Going automation revisions, 480 hours. FR Y–14 Attestation Implementation, 4,800 hours; and On-going audit and review, 2,560 hours.

Number of respondents: 39.

Legal authorization and confidentiality: The FR Y–14 series of reports are authorized by section 165 of the Dodd-Frank Act, which requires the Board to ensure that certain firms and nonbank financial companies supervised by the Board are subject to enhanced risk-based and leverage standards in order to mitigate risks to the financial stability of the United States (12 U.S.C. 5365). Additionally, Section 5 of the Bank Holding Company Act authorizes the Board to issue regulations and conduct information collections with regard to the supervision of BHCs (12 U.S.C. 1844).

With regard to the CFO-level attestation requirement, which is intended to improve accountability and accuracy and heighten requirements for internal control, the Board has provided sufficient description and justification to require such attestation from respondents, consistent with the aforementioned statutory authorities.

As these data are collected as part of the supervisory process, they are subject to confidential treatment under exemption 8 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(8)). In addition, commercial and financial information contained in these information collections may be exempt from disclosure under exemption 4 of FOIA (5 U.S.C. 552(b)(4)), if disclosure would likely have the effect of (1) impairing the government's ability to obtain the necessary information in the future, or (2) causing substantial harm to the competitive position of the respondent. Such exemptions would be made on a case-by-case basis. Such exemptions would be made on a case-by-case basis.

Abstract: The data collected through the FR Y–14A/Q/M schedules provide the Board with the additional information and perspective needed to help ensure that large BHCs and IHCs have strong, firm-wide risk measurement and management processes supporting their internal assessments of capital adequacy and that their capital resources are sufficient given their business focus, activities, and resulting risk exposures. The annual CCAR exercise is also complemented by other Board supervisory efforts aimed at enhancing the continued viability of large firms, including continuous monitoring of firms' planning and management of liquidity and funding resources and regular assessments of credit, market and operational risks, and associated risk management practices. Information gathered in this data collection is also used in the supervision and regulation of these financial institutions. In order to fully evaluate the data submissions, the Board may conduct follow-up discussions with or request responses to follow up questions from respondents, as needed.

The Capital Assessments and Stress Testing information collection consists of the FR Y–14A, Q, and M reports. The semi-annual FR Y–14A collects quantitative projections of balance sheet, income, losses, and capital across a range of macroeconomic scenarios and qualitative information on methodologies used to develop internal projections of capital across scenarios.[1] The quarterly FR Y–14Q collects granular data on various asset classes, including loans, securities, and trading assets, and pre-provision net revenue (PPNR) for the reporting period. The monthly FR Y–14M comprises three retail portfolio- and loan-level collections, and one detailed address matching collection to supplement two of the portfolio and loan-level collections.

Current Actions: The Board proposes revising general FR Y–14 requirements and several schedules of the FR Y–14A/Q/M reports. The revisions would be effective with the FR Y–14 reports as-of December 31, 2016, or December 31, 2017, as noted below. For reports as-of December 31, 2017, the proposed changes include applying the attestation requirement to U.S. IHCs that will be subject to the Large Institution Supervision Coordinating Committee (LISCC) framework ("LISCC U.S. IHCs")[2]. For reports as-of December 31, 2016, the Board proposes adding a requirement for firms electing to undertake planned capital adjustments or incremental capital distribution requests to provide updated submissions of the FR Y–14A Schedule A (Summary—Capital) and Schedule C (Regulatory Capital Instruments, RCI) reflecting these adjustments (as detailed below). To facilitate this collection, the Board proposes adding additional items to the FR Y–14A Schedule C (RCI). Finally, the Board proposes to update the FR Y–14A, Schedule A.1.d. (Summary—Capital) to collect items related to the supplementary leverage ratio (SLR), remove and add sub-schedules to the FR Y–14A Schedule E (Operational Risk) to align with applicable guidance, add one item to Schedule A.5 (Summary—Counterparty), and modify items on the

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[1] BHCs that must re-submit their capital plan generally also must provide a revised FR Y–14A in connection with their resubmission.

[2] Further information regarding the LISCC designation is available on the Board's public Web site: *http://www.federalreserve.gov/bankinforeg/large-institution-supervision.htm*

FR Y–14A/Q/M reports to address inconsistencies across schedules and ensure the collection of accurate information. These changes are explained in further detail in the schedule specific sections below.

The FR Y–14A Schedule A.1.d. (Summary—Capital) would be revised for December 31, 2016, to (1) add certain items used to calculate the SLR in alignment with the Board's extension of the initial application of the SLR requirement in the capital plan rule;[3] (2) modify two items; and (3) remove one item. In addition, one item to capture Other Counterparty Losses would be added to Schedule A.5 (Summary—Counterparty) effective December 31, 2016. Finally, Schedule E (Operational Risk) would be revised for December 31, 2016, to (1) remove sub-schedule E.1, BHC Operational Risk Historical Capital, (2) add two new sub-schedules: E.2, Material Risk Identification and E.3, Operational Risk Scenarios, and (3) update outdated methodologies and references.

The FR Y–14Q (quarterly collection) would be revised for December 31, 2016, to add a new column to Schedule B (Securities) to collect the price of the security as a percent of par to enhance supervisory modeling.

Finally, the FR Y–14M (monthly collection) would be revised for December 31, 2016, to modify the definition of Gross Charge-Off Amount on Schedule D (Credit Cards) in order to ensure proper reporting across firms.

These data are, or will be, used to assess the capital adequacy of BHCs and U.S. IHCs using forward-looking projections of revenue and losses to support supervisory stress test models and continuous monitoring efforts, as well as to inform the Board's operational decision-making as it continues to implement the Dodd-Frank Wall Street Reform and Consumer Protection Act.

Proposed Revision to the FR Y–14A/Q/M

The Board proposes to add an attestation requirement to the FR Y–14A/Q/M reports for U.S. IHC respondents that will be subject to the LISCC framework. Foreign banking organizations with non-branch assets of $50 billion or more were required to form a U.S. IHC by July 1, 2016. As of April 2016, the IHCs established by Barclays, Credit Suisse, UBS and Deutsche Bank are expected to be the LISCC U.S. IHC respondents. This requirement would be consistent with the existing attestation requirement applicable to U.S. BHCs subject to the LISCC framework (LISCC respondents).

On September 16, 2015, the Board published a notice in the **Federal Register** proposing to require a Chief Financial Officer (CFO) level attestation for LISCC respondents.[4] On January 21, 2016, the Board finalized the attestation requirement for LISCC respondents, with a phased-in implementation approach beginning with the reports as-of December 31, 2016.[5] The Board proposes applying an attestation requirement to LISCC U.S. IHCs following a similar phased-in implementation approach, effective beginning December 31, 2017, and fully phased in by December 31, 2018. The proposed effective date would provide LISCC U.S. IHCs with time to develop the appropriate internal processes and procedures to fully implement the proposed attestation following the creation of their U.S. IHCs in July 2016, and the first filing of FR Y–14 reports as-of December 31, 2016.

As discussed in the final **Federal Register** notice adopting the attestation requirement for domestic LISCC respondents, the attestation requirement was designed to help ensure that the data reported to the Board were reliable and accurately reflect the firm's exposures.[6] These data are integral to the Board's assessment of the safety and soundness of a banking organization, as the Board uses financial data reported by a banking organization to assess whether the banking organization has the capital necessary to absorb losses under stress.

The Board initially applied the attestation requirement to only LISCC respondents given the added resources required to implement the attestation.[7] Similarly, the Board would propose to apply the attestation requirement only to those U.S. IHCs that will be subject to the LISCC framework, as the resources needed to ensure accurate data are appropriate in light of the risks that the U.S. operations of these firms pose to the financial system.

Under the proposal the attestation would include three parts. First, for projected data reported on the FR Y–14A/Q and for actual data reported on the FR Y–14A/Q/M reports, collectively, the CFO (or equivalent senior officer[8]) of a LISCC U.S. IHC would be required to attest that the reports have been prepared in conformance with the instructions issued by the Board.[9] Second, for actual data, the CFO (or equivalent senior officer) of a LISCC U.S. IHC would be required to attest that senior management is responsible for the internal controls over the reporting of these data, and that the data reported are materially correct to the best of senior management's knowledge. The CFO would also be required to attest that the controls are effective and include those practices necessary to provide reasonable assurance as to the accuracy of these data. The CFO would be required to attest that the controls are audited annually by internal audit or compliance staff, and are assessed regularly by management of the named institution. For the third part, the CFO would be required to agree to report material weaknesses in these internal controls and any material errors or omissions in the data submitted to the Board promptly as they are identified. Both domestic LISCC firms and LISCC U.S. IHCs subject to the attestation requirement should have a policy in place for determining materiality in the context of attesting to material correctness and internal controls.[10]

As indicated above, the Board proposes that the attestation for LISCC U.S. IHCs would follow a phased-in implementation approach beginning December 31, 2017. The attestation submitted with reports as-of December 31, 2017, would relate to the effectiveness of internal controls over submissions for the as-of date and would not include an attestation to submissions through the year. Beginning with the monthly FR Y–14M report submitted on January 31, 2018, and for each monthly, quarterly and semi-annual FR Y–14 report submitted thereafter, respondents would attest to conformance with the FR Y–14 instructions and to the material correctness of data to the best of the respondent's knowledge, and agree to report material weaknesses and any material errors in the data as they are identified. The full attestation requirement, including attestation to the effectiveness of internal controls throughout the previous year, would be effective starting with the reports submitted as-of December 31, 2018. The attestation pages submitted by LISCC U.S. IHCs would be the same as those used by LISCC BHCs.

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[3] *See* 12 CFR 225.8(c)(3), 12 CFR 252.53(b)(3).

[4] *See* 80 FR 55621 (September 16, 2015).

[5] *See* 81 FR 3412 (January 21, 2016).

[6] *See* 80 FR 55621 (September 16, 2015).

[7] As noted in the preamble to the **Federal Register** notice (80 FR 55621, September 16, 2015), the attestation requirement may require respondents to enhance certain systems and processes in order to meet the attestation requirement, such as enhancing information technology infrastructure and adding or modifying internal control frameworks and data governance committees to include accountability and escalation processes, as well as to increase the frequency of audits of internal controls over the FR Y–14A/Q/M reports.

[8] "An equivalent senior officer" refers to a senior officer who functions as the CFO but carries a different title.

[9] The instructions define the scope and content of items that must be reported, and specify that the reports must be filed in accordance with U.S. generally accepted accounting principles (GAAP). The instructions further state that respondents should maintain financial records in such a manner and scope to ensure the FR Y–14A/Q/M reports reflect a fair presentation of the HCs' financial condition and assessment of performance under stressed scenarios.

[10] The materiality policy should include a robust analysis of all relevant quantitative and qualitative considerations, including, but not limited to, the size and effect of the omission or misstatement on firms' projected regulatory capital ratios in stressed scenarios. Qualitative factors may result in a conclusion that a small change in regulatory capital ratios is considered material. Those circumstances might include the repeat occurrence of errors and omissions, the proximity of a firm's regulatory capital ratios to minimum capital requirements, and whether errors and omissions could change a knowledgeable person's view of the adequacy of internal controls over the capital adequacy process.

Proposed Requirement To Submit Adjusted Capital Action Data

The Board proposes to require additional submissions of certain FR Y–14 schedules to collect information on adjustments to planned capital actions and incremental capital distribution from firms that have elected to make such adjustments, effective with the reports as-of December 31, 2016. An ad-hoc process is currently used to collect this information, which is necessary if, for example, firms intend to exercise the option to adjust their planned capital distributions based on the preliminary results of the supervisory quantitative assessment in CCAR.[11] Given the time-sensitive nature of the collection, current manual collection processes, and ongoing need for firms to submit the data, formalizing the requirement as part of the FR Y–14 would reduce operational risk, establish a regular, standard submission process, and account for the burden of providing these data. Additionally, it would formalize a standard process for firms to employ in submitting information regarding requests to make incremental capital distributions above those included in their capital plans.

The proposed requirement includes two components. First, for adjustments to planned capital actions, firms would be required to submit an updated FR Y–14A Schedule A.1.d (Summary, Capital—CCAR) for the BHC Baseline, Supervisory Adverse, and Supervisory Severely Adverse scenarios and an updated FR Y–14A Schedule C (RCI). These submissions would be collected subsequent to the firms' annual FR Y–14 submission in a timeframe communicated by the Board of at least 14 calendar days in advance of the submission. Second, for incremental capital action requests (*i.e.* requests for additional capital distributions in the period between CCAR exercises), firms would be required to resubmit the FR Y–14A Schedule C (RCI). The incremental capital action requests would be submitted at the time a firm seeks approval for or notifies the Board of its intention to make additional capital distributions.

To allow for the collection of the information necessary to understand these adjustments, the Board proposes adding certain items to the FR Y–14A Schedule C (RCI) including: (1) Cash dividends declared on preferred stock, (2) cash dividends declared on common stock, (3) common shares outstanding (Millions), and (4) common dividends per share ($).

Proposed Revisions to the FR Y–14A

The proposed revisions to the FR Y–14A consist of adding data items in accordance with the finalized modifications to the capital plan and stress test rules (Regulation Y and YY),[12] and modifying existing data items to provide more precise information. The limited changes to Schedule A.1.d (Capital) are expected to require relatively minimal additional burden on firms and in the case of the SLR items are required in accordance with mandatory capital planning requirements. The proposed changes to Schedule E (Operational Risk) would balance the increase in burden due to the addition and modification of items to align with expectations outlined in SR Letter 15–18 with the reduction in burden from the elimination of the outdated and unnecessary data collection.

Schedule A (Summary)

Revisions to Schedule A.1.d (Capital) In accordance with the finalized amendments to the capital plan and stress test rules, a firm will be required to estimate its supplementary leverage ratio (SLR) for the DFAST/CCAR planning horizon beginning January 1, 2018.[13] To facilitate the mandatory reporting of this information, it is necessary to add SLR items to the FR Y–14A report. The Board proposes adding two items to the FR Y–14A Summary Schedule (A.1.d, Capital) report as-of December 31, 2016: Supplementary Leverage Ratio Exposure (SLR Exposure) and Supplementary Leverage Ratio (the SLR). The SLR would be a derived field.

In addition, to collect more precise information regarding deferred tax assets (DTAs), the Board proposes modifying one existing item on the FR Y–14A Schedule A.1.d (Summary—Capital) as-of December 31, 2016. The Board proposes changing existing item 111 on Schedule A.1.d. (Summary—Capital), "Deferred tax assets arising from temporary differences that could not be realized through net operating loss carrybacks, net of DTLs, but before related valuation allowances", to "Deferred tax assets arising from temporary differences, net of DTLs." A firm in a net deferred tax liability (DTL) position would report this item as a negative number. This modification would provide more specific information about the components of the "DTAs arising from temporary differences that could not be realized through net operating loss carrybacks, net of related valuation allowances and net of DTLs" subject to the common equity tier 1 capital deduction threshold.

The Board also proposes removing Schedule HC–M, Memoranda item 107, "Total number of bank holding company common shares outstanding", from the FR Y–14A Schedule A (Summary—Capital) with the reports as-of December 31, 2016, to reduce burden on firms. This item provides minimal additional value and therefore, is no longer needed.

Finally, to reduce the risk of inconsistencies in reporting and align with other regulatory reports, certain definitions in the instructions for the FR Y–14A Schedule A.1.d (Summary—Capital) would be clarified or streamlined to reference comparable items on the FR Y–9C.

Revisions to Schedule A.5 (Counterparty) The Board proposes adding the item "Other counterparty losses" to Schedule A.5 (Summary—Counterparty), similar to the item that was removed with the proposal finalized October 1, 2014.[14] The Board provides guidance to respondents to include risks not considered in the supervisory scenarios and the addition of this item will allow these risks to be captured. This change is proposed to be effective with the reports as-of December 31, 2016.

Schedule E (Operational Risk)

The Board proposes several changes to the FR Y–14A Schedule E (Operational Risk) for the reports as-of December 31, 2016, to align with the guidance and expectations contained in recent supervisory letters, notably SR Letter 15–18. SR Letter 15–18 outlines expectations regarding a firm's risk management infrastructure and strength of associated processes.

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[11] The CCAR Instructions provide further information regarding adjustments a BHC may make to its planned capital distributions: *http://www.federalreserve.gov/newsevents/press/bcreg/bcreg20160128a1.pdf.*

[12] *See* 80 FR 75419 (December 2, 2015).

[13] *See* 12 CFR 225.8(c)(3), 12 CFR 252.53(b)(3).

[14] *See* 79 FR 59264 (October 1, 2014).

In order to capture the information surrounding the risk management infrastructure and processes as outlined in SR Letter 15–18, the Board proposes adding two sub-schedules to the FR Y–14A Schedule E (Operational Risk) and modifying the supporting documentation requirements for this schedule effective with the reports as-of December 31, 2016. First, new sub-schedule E.2, Material Risk Identification, would collect information on a firm's material operational risks included in loss projections based on their risk management framework, a component of risk management emphasized in SR Letter 15–18. Second, new sub-schedule E.3, Operational Risk Scenarios, would collect a firm's operational risk scenarios included in the BHC Baseline and BHC Stress projections, a fundamental element of the framework. Finally, the Board recommends updating the requirements for supporting documentation and modifying certain terminology, definitions, and references to align with SR Letter 15–18.

Certain information related to the previous methodology are no longer necessary to collect given the aforementioned change in guidance, resulting in the proposed removal of these items and updating of associated terminology. Sub-schedule E.1 (BHC Operational Risk Historical Capital) would be removed as this schedule pertains to Advanced Measurement Approaches (AMA) methodology and these data are no longer necessary. This change in methodology also results in the removal of two associated columns on the FR Y–14A Schedule A.6 (Operational Risk Scenario Inputs and Projections): Type of Data and Brief Description. References to previous methodology would be updated, including changing the name of a column on the FR Y–14A Schedule A.6 (Operational Risk Scenario Inputs and Projections) from Units of Measure to Risk Segment. These changes would also be effective with the report as-of December 31, 2016.

Proposed Revisions to the FR Y–14Q

The proposed revision to the FR Y–14Q consists of adding an item to more accurately collect information that is currently derived. This proposed change would allow for more accurate and consistent reporting of information with minimal anticipated burden on respondents.

Schedule B (Securities)

For reports as-of December 31, 2016, the Board proposes adding a new column to the FR Y–14Q Schedule B.1 (Securities 1—Main Schedule) to collect the price of the security to more accurately collect price information and thereby enhance supervisory modeling. Because this information is believed to be readily available, the Board estimates this revision would impose minimal additional burden while improving the ability to use these data.

Proposed Revisions to the FR Y–14M

Schedule D (Credit Card)

For reports as-of December 31, 2016, the Board proposes modifying the definition of Item 62, Gross Charge-off Amount—Current month to reflect the intended method of reporting the item and in response to industry comments. The definition would be modified to indicate that all gross charge-offs must be reported regardless of whether they are from purchased or impaired loans by eliminating the reference to allowance for loan and lease losses (ALLL).

Board of Governors of the Federal Reserve System, July 25, 2016.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2016–17876 Filed 7–27–16; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, Office of Public Health Preparedness and Response; Meetings

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

Time and Date: 3 p.m.–5 p.m., EDT, August 19, 2016.

Place: Web conference via Adobe Connect.

Link: https://ophpr-bsc.adobeconnect.com/august2016/.

Dial-In Number: (877)327–8109.

Participant Code: 2108386.

Status: This meeting is open to the public.

Purpose: This Board is charged with providing advice and guidance to the Secretary, HHS, the Assistant Secretary for Health (ASH), the Director, CDC, and the Director, Office of Public Health Preparedness and Response (OPHPR), concerning strategies and goals for the programs and research within OPHPR, monitoring the overall strategic direction and focus of the OPHPR Divisions and Offices, and administration and oversight of peer review of OPHPR scientific programs.

For additional information about the Board, please visit: *http://www.cdc.gov/phpr/science/counselors.htm.*

Matters for Discussion: The meeting will cover administrative updates; updates from the Director, OPHPR; status updates on BSC recommendations from the April 11–12, 2016 BSC Meeting; and deliberation on potential topics for the October 25–26, 2016 BSC Meeting. Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Dometa Ouisley, Office of Science and Public Health Practice, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop D–44, Atlanta, Georgia 30333, Telephone: (404) 639–7450; Facsimile: (404)639–7977; Email: *OPHPR.BSC.Questions@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention, and Agency for Toxic Substances and Disease Registry.

Catherine Ramadei,

Acting Director, Management Analysis and Service Office, Centers for Disease Control and Prevention.

[FR Doc. 2016–17826 Filed 7–27–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Injury Prevention and Control (NCIPC), Board of Scientific Counselors, National Center for Injury Prevention and Control, (BSC, NCIPC)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announce the following meeting of the aforementioned committee.

Times and Dates: 1:00 p.m.–4:45 p.m. EDT, September 7, 2016 (OPEN); 8:30

a.m.–3:30 p.m. EDT, September 8, 2016 (OPEN).

Place: Centers for Disease Control and Prevention, Thomas R. Harkins Global Communication Center, Building 19, Auditorium B–3, 1600 Clifton Road NE., Atlanta, Georgia 30333. This meeting is also accessible by teleconference.

Dial-In Number: 1–877–937–9818, Participant Code: 7551384 Link to Adobe Connect: *https://violenceprevention.adobeconnect.com/bcs2/.*

Status: This meeting is open to the public limited only by the space and ports available. The meeting room accommodates 200 participants and there will be 100 ports available. There will be public comment periods at the end of each meeting day; September 7, 2016 from 4:05 p.m.–4:35 p.m. and September 8, 2016 from 1:45 p.m.–2:00 p.m.

Purpose: The Board will: (1) Conduct, encourage, cooperate with, and assist other appropriate public health authorities, scientific institutions, and scientists in the conduct of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases, and other impairments; (2) assist States and their political subdivisions in preventing and suppressing communicable and non-communicable diseases and other preventable conditions and in promoting health and well-being; and (3) conduct and assist in research and control activities related to injury.

The Board of Scientific Counselors makes recommendations regarding policies, strategies, objectives, and priorities; and reviews progress toward injury prevention goals and provides evidence in injury prevention-related research and programs. The Board also provides advice on the appropriate balance of intramural and extramural research, the structure, progress and performance of intramural programs. The Board is designed to provide guidance on extramural scientific program matters, including the: (1) Review of extramural research concepts for funding opportunity announcements; (2) conduct of Secondary Peer Review of extramural research grants, cooperative agreements, and contracts applications received in response to the funding opportunity announcements as it relates to the Center's programmatic balance and mission; (3) submission of secondary review recommendations to the Center Director of applications to be considered for funding support; (4) review of research portfolios, and (5) review of program proposals.

Matters for Discussion: The Board of Scientific Counselors will discuss science matters to include research strategies needed to guide the Center's focus, as well as an update from the BSC, Pediatric Mild Traumatic Brain Injury (TBI) Work Group on its considerations for the Pediatric TBI Guideline project. The workgroup report on the protocol and systematic review of the acute identification, diagnosis, and management of children with mild Traumatic Brain Injury guideline will be posted to the BSC Web site prior to the meeting; *http://www.cdc.gov/injury/bsc/index.html.*

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Gwendolyn H. Cattledge, Ph.D., M.S.E.H., Deputy Associate Director for Science, NCIPC, CDC, 4770 Buford Highway, NE., Mailstop F–63, Atlanta, GA 30341, Telephone (770) 488–1430; Email: *ncipcbsc@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Catherine Ramadei,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2016–17797 Filed 7–27–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Request for Nominations of Candidates To Serve on the Advisory Committee to the Director, Centers for Disease Control and Prevention (ACD, CDC)

The Centers for Disease Control and Prevention (CDC) is soliciting nominations for possible membership on the ACD, CDC. ACD, CDC consists of 15 experts in fields related to health policy, public health, global health, preparedness, preventive medicine, the faith-based and community-based sector, and allied fields, who are selected by the Secretary of the U.S. Department of Health and Human Services (HHS). The committee advises the HHS Secretary and the CDC Director concerning policy and broad strategies that will enable CDC to fulfill its mission of protecting health through health promotion, prevention, and preparedness. The committee recommends ways to prioritize CDC's activities, improve results, and address health disparities. It also provides guidance to help CDC work more effectively with its various private and public sector constituents to make health protection a practical reality.

Nominations are being sought for individuals who have the expertise and qualifications necessary to contribute to accomplishment of the committee's objectives. Nominees will be selected by the HHS Secretary or designee from authorities knowledgeable in the fields of public health as well as from the general public. Federal employees will not be considered for membership. Members may be invited to serve for terms of up to four years.

The U.S. Department of Health and Human Services policy stipulates that committee membership be balanced in terms of points of view represented and the committee's function. Consideration will be given to a broad representation of geographic areas. Appointments shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, gender identity, HIV status, disability, and cultural, religious, or socioeconomic status. Nominees must be U.S. citizens and cannot be full-time employees of the U.S. Government. Current participation on federal workgroups or prior experience serving on a federal advisory committee does not disqualify a candidate; however, HHS policy is to avoid excessive individual service on advisory committees and multiple committee memberships. Committee members are Special Government Employees, requiring the filing of financial disclosure reports at the beginning and annually during their terms. CDC reviews potential candidates for ACD, CDC membership each year and provides a slate of nominees for consideration to the Secretary of HHS for final selection. HHS notifies selected candidates of their appointment near the start of the term in July 2017 or as soon as the HHS selection process is completed. Note that the need for different expertise varies from year to year and a candidate who is not selected in one year may be reconsidered in a subsequent year.

Nominees must be U.S. citizens and cannot be full-time employees of the U.S. Government. Candidates should submit the following items:

- Current *curriculum vitae,* including complete contact information (name, affiliation, mailing address, telephone number, and email address);

- A letter of recommendation stating the qualifications of the candidate.

Nomination materials must be postmarked by August 12, 2016 and sent to *ACDirector@cdc.gov,* or to Tracie Strength, Office of the Chief of Staff, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop D14, Atlanta, Georgia, 30329. Please direct questions to Tracie at (404) 498–6482.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Catherine Ramadei,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2016–17794 Filed 7–27–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review; Cancelation

This is to announce the cancelation of a meeting, Operations Research (Implementation Science) for Strengthening Global Health Protection, Funding Opportunity Announcement (FOA) GH16–007, initial review.

SUMMARY: This meeting was announced in the **Federal Register** on July 14, 2016, 81 FR 45506. This meeting is canceled in its entirety.

FOR FURTHER INFORMATION CONTACT: Hylan Shoob, Ph.D., Scientific Review Officer, CDC, 1600 Clifton Road NE., Mailstop D–69, Atlanta, Georgia 30333, Telephone: (404) 639–4796, *HShoob@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Catherine Ramadei,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2016–17827 Filed 7–27–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)—Advisory Council for the Elimination of Tuberculosis (ACET)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee.

Time and Date: 10:00 a.m.–3:30 p.m., EDT, August 24, 2016.

Place: Corporate Square, Building 8, 1st Floor Conference Room, Atlanta, Georgia 30329. This meeting is also accessible by Web conference.

Toll free number +1 877–951–7311, Participant Code: 4727233.

URL for Web conference access: https://www.mymeetings.com/nc/join.php?i=PW9031041&p=4727233&t=c.

Status: This meeting is open to the public, limited only by the meeting room space and Web ports available. The meeting room accommodates 100 people and there will be 100 Web conference ports available. Persons who desire to make an oral statement may request it at the time of the public comment period on August 24, 2016 at 3:20 p.m. (EDT). Public participation and the ability to comment will be limited as time permits.

Purpose: This council advises and makes recommendations to the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the elimination of tuberculosis (TB). Specifically, the Council makes recommendations regarding policies, strategies, objectives, and priorities; addresses the development and application of new technologies; and reviews the extent to which progress has been made toward eliminating tuberculosis.

Matters for Discussion: Agenda items include the following topics: (1) Division of Tuberculosis Elimination's Communication Plan for U.S. Preventive Services Task Force (USPSTF) Recommendations; (2) Analysis of TB Surveillance Data; (3) Update on Molecular Testing; (4) Updates from Workgroups; and (5) other Tuberculosis-related Issues.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Margie Scott-Cseh, Committee Management Specialist, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop: E–07, Atlanta, Georgia 30333, telephone (404) 639–8317; Email: *zkr7@cdc.gov*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Catherine Ramadei,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 2016–17795 Filed 7–27–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Chronic Disease Prevention and Health Promotion, Interagency Committee on Smoking and Health (ICSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (P.L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned committee.

Time and Date: 9:00 a.m.–4:30 p.m., EDT, August 23, 2016.

Place: U.S. Department of Health and Human Services, Hubert H. Humphrey Building, Room 800 located at 200 Independence Avenue SW., Washington, DC 20201. Telephone: (202) 245–0552. This meeting is also accessible by teleconference.

Login information for teleconference is as follows:

Toll Free Phone#: (800)988–0209.

Conference number: PW9322824.

Participant passcode: 5816979.

Participant URL: https://www.mymeetings.com/nc/join.php?i=PW9322824&p=5816979&t=c.

Status: Open to the public, limited only by the space and telephone lines available. The meeting room accommodates 100 people and there will be 50 telephone lines available.

Purpose: The committee advises the Secretary, Department of Health and Human Services, and the Assistant Secretary for Health in the (a) coordination of all research and education programs and other activities within the Department and with other federal, state, local and private agencies, and (b) establishment and maintenance of liaison with appropriate private entities, federal agencies, and state and local public health agencies with respect to smoking and health activities.

Matters for Discussion: The topic of the meeting is "Increasing Smoke-free and Tobacco-free Environments." The objectives of the meeting are to assess the progress of expanding smoke-free and tobacco-free environments 10 years after the landmark 2006 Surgeon General's Report on the health consequences of exposure to secondhand smoke, and to identify specific federal actions that can be taken to further our progress.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Substantive program information as well as summaries of the meeting and roster of committee members may be obtained from the internet at *www.cdc.gov/tobacco* or from Ms. Monica L. Swann, Management and Program Analyst, National Center for Chronic Disease Prevention and Health Promotion, CDC, 395 E. Street SW., Washington, DC 20024. Telephone: (202) 245–0552.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Catherine Ramadei,

Acting Director, Management Analysis and Services Office Centers for Disease Control and Prevention.

[FR Doc. 2016–17799 Filed 7–27–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services

Notice of Opportunity for Hearing on Compliance of Arkansas State Plan Provisions Concerning Provision of Benefits During a Reasonable Opportunity Period With Titles XI and XIX (Medicaid) of the Social Security Act

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of Opportunity for a Hearing Compliance of Arkansas Medicaid State Plan—Provision of Benefits During a Reasonable Opportunity Period.

CLOSING DATE: Requests to participate in the hearing as a party must be received by the presiding officer by August 29, 2016.

FOR FURTHER INFORMATION CONTACT: Benjamin R. Cohen, Hearing Officer, Centers for Medicare & Medicaid Services, 2520 Lord Baltimore Drive, Suite L, Baltimore, MD 21244.

SUPPLEMENTARY INFORMATION: This notice announces the opportunity for an administrative hearing concerning the finding of the Administrator of the Centers for Medicare & Medicaid Services (CMS) that the State of Arkansas is not providing Medicaid benefits during a reasonable opportunity period.

Section 1902(a)(46) of the Social Security Act (the Act) requires state plans for medical assistance to provide "that information is requested and exchanged for purposes of income and eligibility verification in accordance with a State system which meets the requirements of section 1137 of this Act." Section 1137(d) of the Act and regulations at 42 CFR 435.911(c) require that the state agency provide a reasonable opportunity period to individuals who are determined otherwise eligible for Medicaid but for whom the state agency is unable to promptly verify satisfactory immigration status. In its approved State Plan Amendment (SPA) 13–0018, the Arkansas Department of Human Services (DHS) provides assurance that it provides Medicaid to citizens and nationals of the United States and to certain non-citizens, including during a reasonable opportunity period pending verification of their citizenship, national status or satisfactory immigration status, in accordance with the requirements of sections 1902(a)(46), 1902(ee), 1903(x) and 1137(d) of the Act. Despite such assurance in the Medicaid state plan, it is CMS' understanding based on numerous discussions and interactions with the state that Arkansas is not providing Medicaid benefits to individuals who declared under penalty of perjury that they are in a satisfactory immigration status, have met all other eligibility requirements for Medicaid in the state, and are pending verification of their immigration status.

With a formal determination by the CMS Administrator that the Arkansas DHS has failed to comply substantially with these requirements, made after a hearing or absent a hearing request, CMS will begin this FFP withholding and it will continue until the Arkansas DHS comes into compliance with the requirement to provide Medicaid benefits during a reasonable opportunity period for otherwise eligible non-citizens who have declared under penalty of perjury that they are in a satisfactory immigration status.

Arkansas submitted state plan amendment (SPA) Transmittal Number 13–0018 on September 23, 2013, which described the Arkansas DHS's policies and practices related to citizenship and non-citizen eligibility, including the assurance that the Arkansas DHS provides Medicaid benefits during the reasonable opportunity period to individuals who have declared under penalty of perjury that they are in a satisfactory immigration status pending verification of such status. During the review of this SPA, CMS learned that the Arkansas DHS was not providing Medicaid benefits during a reasonable opportunity period to individuals who have declared under penalty of perjury that they are in a satisfactory immigration status and who meet all other eligibility requirements in the state, pending verification of such status. Throughout 2014 and 2015, CMS and Arkansas engaged in extensive technical assistance discussions. CMS sent a letter to the Arkansas DHS on April 1, 2015, reiterating the requirement for Arkansas to comply with the statute and regulations. During this time, CMS received multiple draft corrective action plans (CAPs) from Arkansas that set out schedules to come into compliance with section 1137(d) of the Act by July 1, 2014, October 2015, April 2016, and, most recently, August 2016.

On November 3, 2015, CMS approved Arkansas' SPA 13–0018. At the same time, CMS issued a companion letter informing Arkansas that, if it did not demonstrate compliance with these requirements within 30 days of the date of the letter, CMS would initiate formal compliance proceedings. To date, CMS has not received evidence of compliance with the requirement to provide Medicaid benefits to non-citizens during a reasonable opportunity period.

The notice to Arkansas containing the details concerning this compliance issue, the proposed withholding of FFP, opportunity for a hearing, and possibility of postponing and ultimately avoiding withholding by coming into compliance, reads as follows:

Dear Ms. Stehle:

This letter provides notice that the Centers for Medicare & Medicaid Services (CMS) has found a serious issue of noncompliance because the Arkansas Department of Human Services (DHS) is not providing Medicaid benefits during a reasonable opportunity period as required by section 1137(d) of the Social Security Act (the Act) and regulations at 42 CFR. § 435.911(c).

Pursuant to section 1904 of the Act and 42 CFR 430.35, a portion of the federal financial participation (FFP) of the administrative costs associated with the operation of the Arkansas Medicaid program will be withheld. However, CMS is first providing the Arkansas DHS with an opportunity for a hearing on this withholding decision. With a formal determination by the CMS Administrator that the Arkansas DHS has failed to comply substantially with these requirements, made after a hearing or absent a hearing request, CMS will begin this FFP withholding and it will continue until the Arkansas DHS comes into compliance with the requirement to provide Medicaid benefits during a reasonable opportunity period for otherwise eligible non-citizens who have declared under penalty of perjury that they are in a satisfactory immigration status. The details of the finding, proposed withholding, opportunity for the Arkansas DHS to request a hearing on the finding, and possibility of postponing, and ultimately avoiding, withholding by coming into compliance are described below.

CMS learned of the Arkansas DHS' non-compliance with section 1137(d) of the Act and regulations at 42 CFR 435.911(c) during the review of State Plan Amendment (SPA) Transmittal Number 13–0018. Section 1902(a)(46) of the Act requires state plans for medical assistance to provide "that information is requested and exchanged for purposes of income and eligibility verification in accordance with a State system which meets the requirements of section 1137 of this Act." Section 1137(d) of the Act requires that the state agency provide a reasonable opportunity period to individuals who are determined otherwise eligible for Medicaid but for whom the state agency is unable to promptly verify satisfactory immigration status. See also, 42 CFR. § 435.911(c). In the approved SPA 13–0018, the Arkansas DHS provides assurance that it provides Medicaid to citizens and nationals of the United States and to certain non-citizens, including during a reasonable opportunity period pending verification of their citizenship, national status or satisfactory immigration status, in accordance with the requirements of sections 1902(a)(46), 1902(ee), 1903(x) and 1137(d) of the Act. Despite such assurance in the Medicaid state plan, it is our understanding that the Arkansas DHS is not providing Medicaid benefits to individuals who declare under penalty of perjury that they are in a satisfactory immigration status, meet all other eligibility requirements for Medicaid in the state, and are pending verification of such status.

In processing SPA 13–0018, CMS and the Arkansas DHS discussed this issue on October 10, 2013, and again on December 9, 2013, and the Arkansas DHS acknowledged that it is not furnishing benefits during the reasonable opportunity period to individuals who declare under penalty of perjury that they are in a satisfactory immigration status. A formal Request for Additional Information (RAI) was issued on December 20, 2013, which requested a description of the steps the Arkansas DHS would take to implement the change, a timeline by which the steps would be accomplished and a date by which the changes will be completed to be in compliance with section 1137(d) of the Act. CMS also sent a letter to the Arkansas DHS on April 1, 2015, reiterating the requirement for the Arkansas DHS to comply with the statute and regulations.

Throughout 2014 and 2015, CMS and the Arkansas DHS engaged in extensive technical assistance discussions. During this time, CMS received multiple draft corrective action plans (CAPs) from the Arkansas DHS that set out schedules for compliance with section 1137(d) of the Act, including dates of compliance by July 1, 2014, October 2015, and April 2016. The Arkansas DHS formally responded to the December 20, 2013, RAI on October 7, 2015. The RAI response included a revised schedule for compliance with section 1137(d) of the Act by April of 2016. On November 3, 2015, CMS approved Arkansas' SPA 13–0018, which describes the Arkansas DHS's policies and practices related to citizenship and non-citizen eligibility, including the assurance that the Arkansas DHS is providing Medicaid benefits during the reasonable opportunity period to individuals who have declared under penalty of perjury that they are in a satisfactory immigration status pending verification of such status. At the same time, CMS issued a companion letter informing the Arkansas DHS that, if it did not demonstrate compliance with these requirements within 30 days of the date of the letter, CMS would initiate formal compliance proceedings. The Arkansas DHS did not come into compliance by the specified date and on February 23, 2016, submitted a revised timeline for compliance with section 1137(d) of the Act, with a compliance date of August 2016.

The Arkansas DHS' submission of its quarterly expenditure reports through the CMS–64 includes a certification that the Arkansas DHS is operating under the authority of its approved Medicaid state plan. However, at this time, CMS has not received information from the Arkansas DHS providing evidence of compliance with its approved state plan, section 1137(d) of the Act and regulations at 42 CFR 435.911(c).

In light of the Arkansas DHS' non-compliance with section 1137(d) of the Act, CMS is moving forward with a formal determination of substantial noncompliance with federal requirements described in section 1137(d) of the Act and the regulations at 42 CFR 435.911(c) to provide Medicaid coverage to otherwise eligible non-citizens pending verification of their satisfactory immigration status during a reasonable opportunity period if the individual meets all other eligibility criteria for Medicaid. Subject to the state's opportunity for a hearing, CMS will withhold a portion of federal financial participation (FFP) from the Arkansas DHS' quarterly claim of expenditures for administrative costs until such time as the Arkansas DHS is and continues to be in compliance with the federal requirements. The withholding will initially be three percent of the federal share of the Arkansas DHS' quarterly claim for administrative expenditures, an amount that was developed based on the proportion of total state Medicaid expenditures that are used for expenditures for eligibility determinations, as reported on Form CMS–64.10 Line 50. The withholding percentage will increase by two percentage points (*i.e.* 5 percent, 7 percent, etc.) for every quarter in which the Arkansas DHS remains out of compliance, up to a maximum withholding percentage of 100 percent (of total administrative expenditures). The withholding will end when the Arkansas DHS fully and satisfactorily implements a corrective action plan to bring its procedures to process eligibility determinations under its Medicaid program into compliance with the federal requirements.

The state has 30 days from the date of this letter to request a hearing. As specified in the accompanying **Federal Register** notice, the Arkansas DHS has an opportunity for an administrative hearing prior to this determination becoming final. However, the Arkansas DHS must request a hearing. If a request for a hearing is submitted timely, the hearing will be convened by the Hearing Officer designated below no later than 60 days after the date of the **Federal Register** notice, or a later date by agreement of the parties and the Hearing Officer, at the CMS Regional Office in Dallas, Texas, in accordance with the procedures set forth in federal regulations at 42 CFR part 430, subpart D. The issue in any such hearing will be whether benefits are being provided during a reasonable opportunity period to individuals who have declared under penalty of perjury that they are in a to a satisfactory immigration status pending verification of such status, if they meet all other eligibility requirements, in accordance with the state plan and 42 CFR 435.911(c). Any request for such a hearing should be sent to the designated Hearing Officer. The Hearing Officer also should be notified if the Arkansas DHS requests a hearing but cannot meet the timeframe expressed in this notice. The Hearing Officer designated for this matter is: Benjamin R. Cohen, Hearing Officer, Centers for Medicare & Medicaid Services, 2520 Lord Baltimore Drive, Suite L, Baltimore, MD 21244.

If the Arkansas DHS plans to come into compliance with the approved state plan, the Arkansas DHS should submit, within 30 days of the date of this letter, an explanation of how the Arkansas DHS plans to come into compliance with federal requirements and the timeframe for doing so. If that explanation is satisfactory, CMS may consider postponing any requested hearing, which could also delay the imposition of the withholding of funds as described above. Our goal is to have the Arkansas DHS come into compliance, and CMS continues to be available to provide technical assistance to the Arkansas DHS in achieving this outcome.

Should you not request a hearing within 30 days, a notice of withholding will be sent to you and the withholding of federal funds will begin as described above.

If you have any questions or wish to discuss this determination further, please contact: Bill Brooks, Associate Regional Administrator, Division of Medicaid and Children's Health Operations, CMS Dallas Regional Office, 1301 Young Street, Suite 714, Dallas, TX 75202, 214–767–4461.

Sincerely,
Andrew M. Slavitt
Acting Administrator

(Catalog of Federal Domestic Assistance Program No. 13.714, Medicaid Assistance Program.)

Dated: July 22, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016–17923 Filed 7–27–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1667–PN]

Medicare Program; Request for an Exception to the Prohibition on Expansion of Facility Capacity Under the Hospital Ownership and Rural Provider Exceptions to the Physician Self-Referral Prohibition

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed notice.

SUMMARY: The Social Security Act prohibits a physician-owned hospital from expanding its facility capacity, unless the Secretary of the Department of Health and Human Services (the Secretary) grants the hospital's request for an exception to that prohibition after considering input on the hospital's request from individuals and entities in the community where the hospital is located. The Centers for Medicare & Medicaid Services (CMS) has received a request from a physician-owned hospital for an exception to the prohibition against expansion of facility capacity. This notice solicits comments on the request from individuals and entities in the community in which the physician-owned hospital is located. Community input may inform our determination regarding whether the requesting hospital qualifies for an exception to the prohibition against expansion of facility capacity.

DATES: *Comment Date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 29, 2016.

ADDRESSES: In commenting, please refer to file code CMS–1667–PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this exception request to *http://www.regulations.gov.* Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1667–PN, P.O. Box 8010, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Department of Health and Human Services, Attention: CMS–1667–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: *POH-ExceptionRequests@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments

All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

We will allow stakeholders 30 days from the date of this notice to submit written comments. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of this notice, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, please phone 1–800–743–3951.

I. Background

Section 1877 of the Social Security Act (the Act), also known as the physician self-referral law—(1) prohibits a physician from making referrals for certain "designated health services" (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless the requirements of an applicable exception are satisfied; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those DHS furnished as a result of a prohibited referral.

Section 1877(d)(2) of the Act provides an exception for physician ownership or investment interests in rural providers (the "rural provider exception"). In order for an entity to qualify for the rural provider exception, the DHS must be furnished in a rural area (as defined in section 1886(d)(2) of the Act) and substantially all the DHS furnished by the entity must be furnished to individuals residing in a rural area.

Section 1877(d)(3) of the Act provides an exception, known as the hospital ownership exception, for physician ownership or investment interests held in a hospital located outside of Puerto Rico, provided that the referring physician is authorized to perform services at the hospital and the ownership or investment interest is in the hospital itself (and not merely in a subdivision of the hospital).

Section 6001(a)(3) of the Patient Protection and Affordable Care Act (Pub. L. 111–148) as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (hereafter referred to together as "the Affordable Care Act") amended the rural provider and hospital ownership exceptions to the physician self-referral prohibition to impose additional restrictions on physician ownership and investment in hospitals and rural providers. Since March 23, 2010, a physician-owned hospital that seeks to avail itself of either exception is prohibited from expanding facility capacity unless it qualifies as an "applicable hospital" or "high Medicaid facility" (as defined in sections 1877(i)(3)(E), (F) of the Act and 42 CFR 411.362(c)(2), (3) of our regulations) and has been granted an exception to the prohibition by the Secretary of the Department of Health and Human Services (the Secretary). Section 1877(i)(3)(A)(ii) of the Act provides that individuals and entities in the community in which the provider requesting the exception is located must have an opportunity to provide input with respect to the provider's application for the exception. For further information, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Physician_Owned_Hospitals.html.*

II. Exception Request Process

On November 30, 2011, we published a final rule in the **Federal Register** (76 FR 74122, 74517 through 74525) that, among other things, finalized § 411.362(c), which specified the process for submitting, commenting on, and reviewing a request for an exception to the prohibition on expansion of facility capacity. We published a subsequent final rule in the **Federal Register** on November 10, 2014 (79 FR 66770) that made certain revisions. These revisions included, among other things, permitting the use of data from an external data source or data from the Hospital Cost Report Information System (HCRIS) for specific eligibility criteria.

As stated in regulations at § 411.362(c)(5), we will solicit community input on the request for an exception by publishing a notice of the request in the **Federal Register**. Individuals and entities in the hospital's community will have 30 days to submit comments on the request. Community input must take the form of written comments and may include documentation demonstrating that the physician-owned hospital requesting the exception does or does not qualify as an "applicable hospital" or "high Medicaid facility," as such terms are defined in § 411.362(c)(2) and (3). In the November 30, 2011 final rule (76 FR 74522), we gave examples of community input, such as documentation demonstrating that the hospital does not satisfy one or more of the data criteria or that the hospital discriminates against beneficiaries of Federal health programs; however, we noted that these were examples only and that we will not restrict the type of community input that may be submitted. If we receive timely comments from the community, we will notify the hospital, and the hospital will have 30 days after such notice to submit a rebuttal statement (§ 411.362(c)(5)).

A request for an exception to the facility expansion prohibition is considered complete as follows:

- If the request, any written comments, and any rebuttal statement include only HCRIS data: (1) The end of the 30-day comment period if CMS receives no written comments from the community; or (2) the end of the 30-day rebuttal period if CMS receives written comments from the community, regardless of whether the physician-owned hospital submitting the request submits a rebuttal statement (§ 411.362(c)(5)(i)).
- If the request, any written comments, or any rebuttal statement include data from an external data source, no later than: (1) 180 Days after the end of the 30-day comment period if CMS receives no written comments from the community; and (2) 180 days after the end of the 30-day rebuttal period if CMS receives written comments from the community, regardless of whether the physician-owned hospital submitting the request submits a rebuttal statement (§ 411.362(c)(5)(ii)).

If we grant the request for an exception to the prohibition on expansion of facility capacity, the expansion may occur only in facilities on the hospital's main campus and may not result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed to exceed 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds (§ 411.362(c)(6)). The CMS decision to grant or deny a hospital's request for an exception to the prohibition on expansion of facility capacity must be published in the **Federal Register** in accordance with our regulations at § 411.362(c)(7).

III. Hospital Exception Request

As permitted by section 1877(i)(3) of the Act and our regulations at § 411.362(c), the following physician-owned hospital has requested an exception to the prohibition on expansion of facility capacity:

Name of Facility: Deaconess Women's Hospital of Southern Indiana d/b/a The Women's Hospital.

Location: 4199 Gateway Blvd., Newburgh, IN 47630.

Basis for Exception Request: High Medicaid Facility.

We seek comments on this request from individuals and entities in the community in which the hospital is located. We encourage interested parties to review the hospital's request, which is posted on the CMS Web site at: *http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Physician_Owned_Hospitals.html.* We especially welcome comments regarding whether the hospital qualifies as a high Medicaid facility. Under § 411.362(c)(3), a high Medicaid facility is a hospital that satisfies all of the following criteria:

- Is not the sole hospital in the county in which the hospital is located.

- With respect to each of the 3 most recent 12-month periods for which data are available as of the date the hospital submits its request, has an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located.
- Does not discriminate against beneficiaries of federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

Individuals and entities wishing to submit comments on the hospital's request should review the **DATES** and **ADDRESSES** sections and state whether or not they are in the community in which the hospital is located.

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

V. Response to Public Comments

We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Dated: July 14, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016–17928 Filed 7–27–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0007]

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2017

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates and payment procedures for fiscal year (FY) 2017 animal drug user fees. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Animal Drug User Fee Amendments of 2013 (ADUFA III), authorizes FDA to collect user fees for certain animal drug applications and supplements, for certain animal drug products, for certain establishments where such products are made, and for certain sponsors of such animal drug applications and/or investigational animal drug submissions. This notice establishes the fee rates for FY 2017.

FOR FURTHER INFORMATION CONTACT: Visit FDA's Web site at *http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm* or contact Lisa Kable, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6888. For general questions, you may also email the Center for Veterinary Medicine (CVM) at: *cvmadufa@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 740 of the FD&C Act (21 U.S.C. 379j–12) establishes four different types of user fees: (1) Fees for certain types of animal drug applications and supplements; (2) annual fees for certain animal drug products; (3) annual fees for certain establishments where such products are made; and (4) annual fees for certain sponsors of animal drug applications and/or investigational animal drug submissions (21 U.S.C. 379j–12(a)). When certain conditions are met, FDA will waive or reduce fees (21 U.S.C. 379j–12(d)).

For FY 2014 through FY 2018, the FD&C Act establishes aggregate yearly base revenue amounts for each fiscal year (21 U.S.C. 379j–12(b)(1)). Base revenue amounts established for years after FY 2014 are subject to adjustment for inflation and workload (21 U.S.C. 379j–12(c)). Fees for applications, establishments, products, and sponsors are to be established each year by FDA so that the percentages of the total revenue that are derived from each type of user fee will be as follows: Revenue from application fees shall be 20 percent of total fee revenue; revenue from product fees shall be 27 percent of total fee revenue; revenue from establishment fees shall be 26 percent of total fee revenue; and revenue from sponsor fees shall be 27 percent of total fee revenue (21 U.S.C. 379j–12(b)(2)).

For FY 2017, the animal drug user fee rates are: $350,700 for an animal drug application; $175,350 for a supplemental animal drug application for which safety or effectiveness data are required and for an animal drug application subject to the criteria set forth in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)); $8,195 for an annual product fee; $111,900 for an annual establishment fee; and $103,100 for an annual sponsor fee. FDA will issue invoices for FY 2017 product, establishment, and sponsor fees by December 31, 2016, and payment will be due by January 31, 2017. The application fee rates are effective for applications submitted on or after October 1, 2016, and will remain in effect through September 30, 2017. Applications will not be accepted for review until FDA has received full payment of application fees and any other animal drug user fees owed under the Animal Drug User Fee program (ADUFA program).

II. Revenue Amount for FY 2017

A. Statutory Fee Revenue Amounts

ADUFA III, Title I of Public Law 113–14, specifies that the aggregate fee revenue amount for FY 2017 for all animal drug user fee categories is $21,600,000 (21 U.S.C. 379j–12(b)(1)(B).).

B. Inflation Adjustment to Fee Revenue Amount

The fee revenue amount established in ADUFA III for FY 2015 and subsequent fiscal years are subject to an inflation adjustment (21 U.S.C. 379j–12(c)(2)).

The component of the inflation adjustment for payroll costs shall be one plus the average annual percent change in the cost of all personnel compensation and benefits (PC&B) paid per full-time equivalent position (FTE) at FDA for the first three of the four preceding fiscal years, multiplied by the proportion of PC&B costs to total FDA costs for the first three of the four preceding fiscal years (see 21 U.S.C. 379j–12(c)(2)(A) and (B)). The data on total PC&B paid and numbers of FTE paid, from which the average cost per FTE can be derived, are published in FDA's Justification of Estimates for Appropriations Committees.

Table 1 summarizes that actual cost and FTE data for the specified fiscal years, and provides the percent change from the previous fiscal year and the average percent change over the first three of the four fiscal years preceding FY 2017. The 3-year average is 1.8759 percent.

TABLE 1—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGE

Fiscal year	2013	2014	2015	3-year average
Total PC&B	$1,927,703,000	$2,054,937,000	$2,232,304,000	
Total FTE	13,974	14,555	15,484	
PC&B per FTE	137,949	141,184	144,168	
Percent Change from Previous Year	1.1690%	2.3451%	2.1136%	1.8759%

The statute specifies that this 1.8759 percent should be multiplied by the proportion of PC&B costs to total FDA costs. Table 2 shows the amount of PC&B and the total amount obligated by FDA for the same 3 FYs.

TABLE 2—PC&B AS A PERCENT OF TOTAL COSTS AT FDA

Fiscal year	2013	2014	2015	3-year average
Total PC&B	$1,927,703,000	$2,054,937,000	$2,232,304,000	
Total Costs	4,151,343,000	4,298,476,000	4,510,565,000	
PC&B Percent	46.4356%	47.8062%	49.4906%	47.9108%

The payroll adjustment is 1.8759 percent multiplied by 47.9108 percent (or 0.8988 percent).

The statute specifies that the portion of the inflation adjustment for non-payroll costs for FY 2017 is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Baltimore, DC-MD-VA-WV; not seasonally adjusted; all items less food and energy; annual index) for the first 3 of the preceding 4 years of available data multiplied by the proportion of all costs other than PC&B costs to total FDA costs (see 21 U.S.C. 379j–12(c)(2)(C)). Table 3 provides the summary data for the percent change in the specified CPI for the Baltimore-Washington area. The data from the Bureau of Labor Statistics is shown in table 3.

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN BALTIMORE-WASHINGTON AREA CPI LESS FOOD AND ENERGY

Year	2013	2014	2015	3-year average
Annual CPI	146.953	149.581	152.242	
Annual Percent Change	1.7588%	1.7883%	1.7790%	1.7754%

To calculate the inflation adjustment for non-pay costs, we multiply the 1.7754 percent by the proportion of all costs other than PC&B to total FDA costs. Since 47.9108 percent was obligated for PC&B as shown in table 2, 52.0892 percent is the portion of costs other than PC&B (100 percent minus 47.9108 percent equals 52.0892 percent). The non-payroll adjustment is 1.7754 percent times 52.0892 percent, or 0.9248 percent.

Next, we add the payroll component (0.8988 percent) to the non-pay component (0.9248 percent), for a total inflation adjustment of 1.8236 percent for FY 2017.

ADUFA III provides for the inflation adjustment to be compounded each fiscal year after FY 2014 (see 21 U.S.C. 379j–12(c)(2)). The factor for FY 2017 (1.8236 percent) is compounded by adding 1 and then multiplying by 1 plus the inflation adjustment factor for FY 2016 (2.1121 percent), as published in the **Federal Register** of August 3, 2015 (80 FR 45993 to 45998), which equals 1.060746 (rounded) (1.018236 times 1.041749) for FY 2017. We then multiply the base revenue amount for FY 2017 ($21,600,000) by 1.060746, yielding an inflation adjusted amount of $22,912,114.

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

A workload adjustment will be calculated to the inflation adjusted fee revenue amount established in ADUFA III for FY 2015 and subsequent fiscal years (21 U.S.C. 379j–12(c)(3)).

FDA calculated the average number of each of the five types of applications and submissions specified in the workload adjustment provision (animal drug applications, supplemental animal drug applications for which data with respect to safety or efficacy are required, manufacturing supplemental animal drug applications, investigational animal drug study submissions, and investigational animal drug protocol submissions) received over the 5-year period that ended on September 30, 2013 (the base years), and the average number of each of these types of applications and submissions over the most recent 5-year period that ended June 30, 2016.

The results of these calculations are presented in the first two columns of table 4. Column 3 reflects the percent change in workload over the two 5-year periods. Column 4 shows the weighting factor for each type of application, reflecting how much of the total FDA animal drug review workload was accounted for by each type of application or submission in the table during the most recent five years. Column 5 is the weighted percent change in each category of workload, and was derived by multiplying the weighting factor in each line in column 4 by the percent change from the base years in column 3. At the bottom right of table 4 the sum of the values in column 5 is added, reflecting a total change in workload of 3.3206 percent for FY 2017. This is the workload adjuster for FY 2017.

TABLE 4—WORKLOAD ADJUSTER CALCULATION

[Numbers may not add due to rounding]

Application type	Column 1	Column 2	Column 3	Column 4	Column 5
	5-year average (base years)	Latest 5-year average	Percent change	Weighting factor	Weighted percent change
New Animal Drug Applications (NADAs)	9.8000	13.4000	36.7347	0.0250	0.9168
Supplemental NADAs with Safety or Efficacy Data	9.6000	12.4000	29.1667	0.0342	0.9971
Manufacturing Supplements	361.0000	324.6000	−10.0831	0.1565	−1.5783
Investigational Study Submissions	216.4000	204.6000	−5.4529	0.6002	−3.2727
Investigational Protocol Submissions	133.6000	179.0000	33.9820	0.1841	6.2577
FY 2017 Workload Adjuster					3.3206

FDA experienced an increase in the number of new animal drug applications (NADAs) and supplemental NADAs with safety or effectiveness data. Over the last several years FDA has seen an increase in the number of animal drug products brought by animal drug sponsors for review in the drug evaluation process. These new animal drug products come from both existing animal drug sponsors as well as sponsors new to the animal drug market. The increase in new animal drug products have contributed to an increase in the number of protocol submissions and NADAs submitted for many novel drug classes and novel indications for both food-producing animals and companion animals. FDA can expect that the increases in reviewed protocols will lead in the near future to an increase in the number of Investigational Study Submissions and NADAs or supplemental NADAs as sponsors work their products through the regulatory review process. Additionally, FDA has seen an increase in the number of animal drug sponsors pursuing multiple changes to their existing NADAs (*e.g.*, new indications, new species, changes in dosage). For this reason we are seeing an increase in the number of supplemental NADAs with safety or effectiveness data. As a result, the statutory revenue amount after the inflation adjustment ($22,912,114) must now be increased by 3.3206 percent to reflect the changes in review workload (workload adjustment), for a total fee revenue target of $23,673,000 (rounded to the nearest thousand dollars).

D. FY 2017 Fee Revenue Amounts

ADUFA III specifies that the revenue amount of $23,673,000 for FY 2017 is to be divided as follows: 20 percent, or a total of $4,734,000 (rounded to the nearest thousand dollars), is to come from application fees; 27 percent, or a total of $6,392,000 (rounded to the nearest thousand dollars), is to come from product fees; 26 percent, or a total of $6,155,000 (rounded to the nearest thousand dollars), is to come from establishment fees; and 27 percent, or a total of $6,392,000 (rounded to the nearest thousand dollars), is to come from sponsor fees (21 U.S.C. 379j–12(b)).

III. Application Fee Calculations for FY 2017

A. Application Fee Revenues and Numbers of Fee-Paying Applications

Each person that submits an animal drug application or a supplemental animal drug application shall be subject to an application fee, with limited exceptions (see 21 U.S.C. 379j–12 (a)(1)). The term "animal drug application" means an application for approval of any new animal drug submitted under section 512(b)(1) (21 U.S.C. 379j–11(1)). A "supplemental animal drug application" is defined as a request to the Secretary to approve a change in an animal drug application which has been approved, or a request to the Secretary to approve a change to an application approved under section 512(c)(2) for which data with respect to safety or effectiveness are required (21 U.S.C. 379j–11(2)). The application fees are to be set so that they will generate $4,734,000 in fee revenue for FY 2017. The fee for a supplemental animal drug application for which safety or effectiveness data are required and for an animal drug application subject to criteria set forth in section 512(d)(4) of the FD&C Act is to be set at 50 percent of the animal drug application fee (21 U.S.C. 379j–12(a)(1)(A)(ii)).

To set animal drug application fees and supplemental animal drug application fees to realize $4,734,000 FDA must first make some assumptions about the number of fee-paying applications and supplements the Agency will receive in FY 2017.

The Agency knows the number of applications that have been submitted in previous years. That number fluctuates from year to year. In estimating the fee revenue to be generated by animal drug application fees in FY 2017, FDA is assuming that the number of applications that will pay fees in FY 2017 will equal the average number of submissions over the five most recent completed years of the ADUFA program (FY 2011 to FY 2015). FDA believes that this is a reasonable approach after 12 completed years of experience with this program.

Over the five most recent completed years, the average number of animal drug applications that would have been subject to the full fee was 7.2. Over this same period, the average number of supplemental applications and applications subject to the criteria set forth in section 512(d)(4) of the FD&C Act that would have been subject to half of the full fee was 12.6.

B. Application Fee Rates for FY 2017

FDA must set the fee rates for FY 2017 so that the estimated 7.2 applications that pay the full fee and the estimated 12.6 supplemental applications and applications subject to the criteria set forth in section 512(d)(4) of the FD&C Act that pay half of the full fee will generate a total of $4,734,000. To generate this amount, the fee for an animal drug application, rounded to the nearest $100, will have to be $350,700, and the fee for a supplemental animal drug application for which safety or effectiveness data are required and for applications subject to the criteria set forth in section 512(d)(4) of the FD&C Act will have to be $175,350.

IV. Product Fee Calculations for FY 2017

A. Product Fee Revenues and Numbers of Fee-Paying Products

The animal drug product fee (also referred to as the product fee) must be paid annually by the person named as the applicant in a new animal drug application or supplemental new animal drug application for an animal drug product submitted for listing under section 510 of the FD&C Act (21 U.S.C. 360), and who had an animal drug application or supplemental animal drug application pending at FDA after September 1, 2003 (21 U.S.C. 379j–12(a)(2)). The term "animal drug product" means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an animal drug application or a supplemental animal drug application has been approved (21 U.S.C. 379j–11(3)). The product fees are to be set so that they will generate $6,392,000 in fee revenue for FY 2017.

To set animal drug product fees to realize $6,392,000, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2017. FDA developed data on all animal drug products that have been submitted for listing under section 510 of the FD&C Act and matched this to the list of all persons who had an animal drug application or supplement pending after September 1, 2003. As of June 2016, FDA estimates that there are a total of 804 products submitted for listing by persons who had an animal drug application or supplemental animal drug application pending after September 1, 2003. Based on this, FDA estimates that a total of 804 products will be subject to this fee in FY 2017.

In estimating the fee revenue to be generated by animal drug product fees in FY 2017, FDA is assuming that 3 percent of the products invoiced, or 24, will not pay fees in FY 2017 due to fee waivers and reductions. FDA has kept this estimate at 3 percent this year, based on historical data over the past 5 completed years of the ADUFA program. Based on experience over the first 12 completed years of the ADUFA program, FDA believes that this is a reasonable basis for estimating the number of fee-paying products in FY 2017.

Accordingly, the Agency estimates that a total of 780 (804 minus 24) products will be subject to product fees in FY 2017.

B. Product Fee Rates for FY 2017

FDA must set the fee rates for FY 2017 so that the estimated 780 products that pay fees will generate a total of $6,392,000. To generate this amount will require the fee for an animal drug product, rounded to the nearest $5, to be $8,195.

V. Establishment Fee Calculations for FY 2017

A. Establishment Fee Revenues and Numbers of Fee-Paying Establishments

The animal drug establishment fee (also referred to as the establishment fee) must be paid annually by the person who: (1) Owns or operates, directly or through an affiliate, an animal drug establishment; (2) is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product submitted for listing under section 510 of the FD&C Act; (3) had an animal drug application or supplemental animal drug application pending at FDA after September 1, 2003; and (4) whose establishment engaged in the manufacture of the animal drug product during the fiscal year (see 21 U.S.C. 379j–12(a)(3)). An establishment subject to animal drug establishment fees is assessed only one such fee per fiscal year. The term "animal drug establishment" is defined as a foreign or domestic place of business which is at one general physical location consisting of one or more buildings all of which are within 5 miles of each other, at which one or more animal drug products are manufactured in final dosage form (21 U.S.C. 379j–11(4)). The establishment fees are to be set so that they will generate $6,155,000 in fee revenue for FY 2017.

To set animal drug establishment fees to realize $6,155,000, FDA must make some assumptions about the number of establishments for which these fees will be paid in FY 2017. FDA developed data on all animal drug establishments and matched this to the list of all persons who had an animal drug application or supplement pending after September 1, 2003. As of June 2016, FDA estimates that there are a total of 62 establishments owned or operated by persons who had an animal drug application or supplemental animal drug application pending after September 1, 2003. Based on this, FDA believes that 62 establishments will be subject to this fee in FY 2017.

In estimating the fee revenue to be generated by animal drug establishment fees in FY 2017, FDA is assuming that 11 percent of the establishments invoiced, or seven, will not pay fees in FY 2017 due to fee waivers and reductions. FDA has reduced this estimate from 12 percent to 11 percent this year, based on historical data over the past 5 completed years. Based on experience over the past 12 completed years of the ADUFA program, FDA believes that this is a reasonable basis for estimating the number of fee-paying establishments in FY 2017.

Accordingly, the Agency estimates that a total of 55 establishments (62 minus 7) will be subject to establishment fees in FY 2017.

B. Establishment Fee Rates for FY 2017

FDA must set the fee rates for FY 2017 so that the estimated 55 establishments that pay fees will generate a total of $6,155,000. To generate this amount will require the fee for an animal drug establishment, rounded to the nearest $50, to be $111,900.

VI. Sponsor Fee Calculations for FY 2017

A. Sponsor Fee Revenues and Numbers of Fee-Paying Sponsors

The animal drug sponsor fee (also referred to as the sponsor fee) must be paid annually by each person who: (1) Is named as the applicant in an animal drug application, except for an approved application for which all subject products have been removed from listing under section 510 of the FD&C Act, or has submitted an investigational animal drug submission that has not been terminated or otherwise rendered inactive and (2) had an animal drug application, supplemental animal drug application, or investigational animal drug submission pending at FDA after September 1, 2003 (see 21 U.S.C. 379j–11(6) and 379j–12(a)(4)). An animal drug sponsor is subject to only one such fee each fiscal year (see 21 U.S.C. 379j–12(a)(4)). The sponsor fees are to be set so that they will generate $6,392,000 in fee revenue for FY 2017.

To set animal drug sponsor fees to realize $6,392,000, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2017. Based on the number of firms that would have met this definition in each of the past 12 completed years of the ADUFA program, FDA estimates that a total of 189 sponsors will meet this definition in FY 2017.

Careful review indicates that 35 percent of these sponsors will qualify for minor use/minor species waiver or reduction (21 U.S.C. 379j–12(d)(1)(D)). Based on the Agency's experience to date with sponsor fees, FDA's current best estimate is that an additional 32 percent will qualify for other waivers or reductions, for a total of 67 percent of the sponsors invoiced, or 127, who will not pay fees in FY 2017 due to fee waivers and reductions. FDA has increased this estimate from 65 percent to 67 percent this year, based on historical data over the past 5 completed years of the ADUFA program. FDA believes that this is a reasonable basis for estimating the number of fee-paying sponsors in FY 2017.

Accordingly, the Agency estimates that a total of 62 sponsors (189 minus 127) will be subject to and pay sponsor fees in FY 2017.

B. Sponsor Fee Rates for FY 2017

FDA must set the fee rates for FY 2017 so that the estimated 62 sponsors that pay fees will generate a total of $6,392,000. To generate this amount will require the fee for an animal drug sponsor, rounded to the nearest $50, to be $103,100.

VII. Fee Schedule for FY 2017

The fee rates for FY 2017 are summarized in Table 5.

TABLE 5—FY 2017 FEE RATES

Animal drug user fee category	Fee rate for FY 2017 ($)
Animal Drug Application Fees:	
Animal Drug Application	350,700
Supplemental Animal Drug Application for Which Safety or Effectiveness Data are Required or Animal Drug Application Subject to the Criteria Set Forth in Section 512(d)(4) of the FD&C Act	175,350
Animal Drug Product Fee	8,195
Animal Drug Establishment Fee[1]	111,900
Animal Drug Sponsor Fee[2]	103,100

[1] An animal drug establishment is subject to only one such fee each fiscal year.
[2] An animal drug sponsor is subject to only one such fee each fiscal year.

VIII. Procedures for Paying the FY 2017 Fees

A. Application Fees and Payment Instructions

The appropriate application fee established in the new fee schedule must be paid for an animal drug application or supplement subject to fees under ADUFA III that is submitted on or after October 1, 2016. Payment must be made in U.S. currency by check, bank draft, U.S. postal money order payable to the order of the Food and Drug Administration, wire transfer, or electronically using *Pay.gov.* The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay* or the *Pay.gov* payment option is available to you after you submit a cover sheet. Once you search for your invoice, click "Pay Now" to be redirected to *Pay.gov.* Note that electronic payment options are based on the balance due. Payment by credit card is available for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be drawn on U.S bank accounts as well as U.S. credit cards.

On your check, bank draft, or U.S. postal money order, please write your application's unique Payment Identification Number (PIN), beginning with the letters AD, from the upper right-hand corner of your completed Animal Drug User Fee Cover Sheet. Also write the FDA post office box number (P.O. Box 979033) on the enclosed check, bank draft, or money order. Your payment and a copy of the completed Animal Drug User Fee Cover Sheet can be mailed to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000.

If payment is made by wire transfer, send payment to: U.S. Department of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, FDA Deposit Account Number: 75060099, U.S. Department of Treasury routing/transit number: 021030004, SWIFT Number: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., 14th Floor, Silver Spring, MD 20993–0002. You are responsible for any administrative costs associated with the processing of a wire transfer. Contact your bank or financial institution about the fee and add it to your payment to ensure that your fee is fully paid.

If you prefer to send a check by a courier, the courier may deliver the check and printed copy of the cover sheet to: U.S. Bank, Attn: Government Lockbox 979033, 1005 Convention Plaza, St. Louis, MO 63101. (**Note:** This address is for courier delivery only. If you have any questions concerning courier delivery contact the U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery.)

The tax identification number of FDA is 53–0196965. (**Note:** In no case should the payment for the fee be submitted to FDA with the application.)

It is helpful if the fee arrives at the bank at least a day or two before the application arrives at FDA's CVM. FDA records the official application receipt date as the later of the following: The date the application was received by FDA's CVM, or the date U.S. Bank notifies FDA that your payment in the full amount has been received, or when the U.S. Treasury notifies FDA of receipt of an electronic or wire transfer payment. U.S. Bank and the U.S. Treasury are required to notify FDA within 1 working day, using the PIN described previously.

B. Application Cover Sheet Procedures

Step One—Create a user account and password. Log on to the ADUFA Web site at *http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm* and, under Tools and Resources, click "The Animal Drug User Fee Cover Sheet" and then click "Create ADUFA User Fee Cover Sheet." For security reasons, each firm submitting an application will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process.

Step Two—Create an Animal Drug User Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your user name and password, complete the steps required to create an Animal Drug User Fee Cover Sheet. One cover sheet is needed for each animal drug application or supplement. Once you are satisfied that the data on the cover sheet is accurate and you have finalized the cover sheet, you will be able to transmit it electronically to FDA and you will be able to print a copy of your cover sheet showing your unique PIN.

Step Three—Send the payment for your application as described in section VIII.A.

Step Four—Please submit your application and a copy of the completed Animal Drug User Fee Cover Sheet to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV–199), 7500 Standish Pl., Rockville, MD 20855.

C. Product, Establishment, and Sponsor Fees

By December 31, 2016, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2017 using this fee schedule. Payment will be due by January 31, 2017. FDA will issue invoices in November 2017 for any products, establishments, and sponsors subject to fees for FY 2017 that qualify for fees after the December 2016 billing.

Dated: July 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–17848 Filed 7–27–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0007]

Animal Generic Drug User Fee Rates and Payment Procedures for Fiscal Year 2017

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fee rates and payment procedures for fiscal year (FY) 2017 generic new animal drug user fees. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Animal Generic Drug User Fee Amendments of 2013 (AGDUFA II), authorizes FDA to collect user fees for certain abbreviated applications for generic new animal drugs, for certain generic new animal drug products, and for certain sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs. This notice establishes the fee rates for FY 2017.

FOR FURTHER INFORMATION CONTACT: Visit FDA's Web site at *http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm,* or contact Lisa Kable, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6888. For general questions, you may also email the Center for Veterinary Medicine (CVM) at *cvmagdufa@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 741 of the FD&C Act (21 U.S.C. 379j–21) establishes three different types of user fees: (1) Fees for certain types of abbreviated applications for generic new animal drugs; (2) annual fees for certain generic new animal drug products; and (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs (21 U.S.C. 379j–21(a)). When certain conditions are met, FDA will waive or reduce fees for generic new animal drugs intended solely to provide for a minor use or minor species indication (21 U.S.C. 379j–21(d)).

For FY 2014 through FY 2018, the FD&C Act establishes aggregate yearly base revenue amounts for each of these fee categories (21 U.S.C. 379j–21(b)). Base revenue amounts established for fiscal years after FY 2014 are subject to adjustment for workload (21 U.S.C. 379j–21(c)). The target revenue amounts for each fee category for FY 2017, after the adjustment for workload, are as follows: For application fees the target revenue amount is $2,835,000; for product fees the target revenue amount is $4,253,000; and for sponsor fees the target revenue amount is $4,253,000.

For FY 2017, the generic new animal drug user fee rates are: $232,400 for each abbreviated application for a generic new animal drug other than those subject to the criteria in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)); $116,200 for each abbreviated application for a generic new animal drug subject to the criteria in section 512(d)(4); $10,200 for each generic new animal drug product; $96,350 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; $72,263 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; and $48,175 for each generic new animal drug sponsor paying 50 percent of the sponsor fee. FDA will issue invoices for FY 2017 product and sponsor fees by December 31, 2016. These fees will be due by January 31, 2017. The application fee rates are effective for all abbreviated applications for a generic new animal drug submitted on or after October 1, 2016, and will remain in effect through September 30, 2017. Applications will not be accepted for review until FDA has received full payment of related application fees and any other fees owed under the Animal Generic Drug User Fee program (AGDUFA program).

II. Revenue Amount for FY 2017

A. Statutory Fee Revenue Amounts

AGDUFA II, Title II of Public Law 113–14, specifies that the aggregate revenue amount for FY 2017 for abbreviated application fees is $1,984,000 and each of the other two generic new animal drug user fee categories, annual product fees and annual sponsor fees, is $2,976,000 each (see 21 U.S.C. 379j–21(b)).

B. Inflation Adjustment to Fee Revenue Amount

The amounts established in AGDUFA II for each year for FY 2014 through FY 2018 include an inflation adjustment; therefore, no further inflation adjustment is required.

C. Workload Adjustment Fee Revenue Amount

For each FY beginning after FY 2014, AGDUFA II provides that statutory fee revenue amounts shall be further adjusted to reflect changes in review workload. (See 21 U.S.C. 379j–21(c)(2).)

FDA calculated the average number of each of the four types of applications and submissions specified in the workload adjustment provision (abbreviated applications for generic new animal drugs, manufacturing supplemental abbreviated applications for generic new animal drugs, investigational generic new animal drug study submissions, and investigational generic new animal drug protocol submissions) received over the 5-year period that ended on September 30, 2013 (the base years), and the average number of each of these types of applications and submissions over the most recent 5-year period that ended on June 30, 2016.

The results of these calculations are presented in the first two columns in table 1. Column 3 reflects the percent change in workload over the two 5-year periods. Column 4 shows the weighting factor for each type of application, reflecting how much of the total FDA generic new animal drug review workload was accounted for by each type of application or submission in the table during the most recent 5 years. Column 5 is the weighted percent change in each category of workload and was derived by multiplying the weighting factor in each line in column 4 by the percent change from the base years in column 3. At the bottom right of table 1, the sum of the values in column 5 is calculated, reflecting a total change in workload of 42.9097 percent for FY 2017. This is the workload adjuster for FY 2017.

TABLE 1—WORKLOAD ADJUSTER CALCULATION

Application type	Column 1 5-year average (base years)	Column 2 Latest 5-year average	Column 3 Percent change	Column 4 Weighting factor	Column 5 Weighted percent change
Abbreviated New Animal Drug Applications (ANADAs)	25.0	29.8	19.2000	0.3730	7.1620
Manufacturing Supplements ANADAs	128.0	145.2	13.4375	0.2667	3.5837
Generic Investigational Study Submissions	23.0	48.0	108.6957	0.2411	26.2031
Generic Investigational Protocol Submissions	17.2	25.8	50.0000	0.1192	5.9609
FY 2017 AGDUFA II Workload Adjuster					42.9097

Over the last year FDA has continued to see more sponsors getting involved in the generic animal drug approval process, including pioneer sponsors. This has contributed to sustained increases in the number of ANADAs, manufacturing supplements, and protocols submitted. Additionally, more sponsors continue to pursue drug approvals that do not qualify for a waiver of the requirement to conduct an in vivo bioequivalence study. For this reason we are seeing a large sustained increase in the number of generic investigational new animal drug study submissions.

As a result, the statutory revenue amount for each category of fees for FY 2017 ($1,984,000 for application fees and $2,976,000 for both product and sponsor fees) must now be increased by 42.9097 percent, for a total fee revenue target in FY 2017 of $11,341,000 (rounded to the nearest thousand dollars) for fees from all three categories. The target for application fee revenue is $1,984,000 times 42.9097 percent, for a total of $2,835,000, rounded to the nearest thousand. The target for product fee revenue is $2,976,000 times 42.9097 percent, for a total of $4,253,000, rounded to the nearest thousand dollars, and the target for sponsor fee revenue is the same as for product fees ($4,253,000, rounded to the nearest thousand dollars).

III. Abbreviated Application Fee Calculations for FY 2017

A. Application Fee Revenues and Numbers of Fee-Paying Applications

Each person that submits an abbreviated application or a supplemental abbreviated application for a generic new animal drug shall be subject to an application fee, with limited exceptions (21 U.S.C. 379j–21(a)(1)). The term "abbreviated application for a generic new animal drug" means an abbreviated application for the approval of any generic new animal drug submitted under section 512(b)(2) (21 U.S.C. 379j–21(k)(1)). A "supplemental abbreviated application for a generic new animal drug" is defined as a request to the Secretary to approve a change in an approved abbreviated application (21 U.S.C. 379j–21(k)(11)). The application fees are to be set so that they will generate $2,835,000 in fee revenue for FY 2017.

To set fees for abbreviated applications for generic new animal drugs to realize $2,835,000, FDA must first make some assumptions about the number of fee-paying abbreviated applications it will receive during FY 2017.

The Agency knows the number of applications that have been submitted in previous years. That number fluctuates from year to year. FDA is making estimates and applying different assumptions for two types of full fee submissions: Original submissions of abbreviated applications for generic new animal drugs and "reactivated" submissions of abbreviated applications for generic new animal drugs. Any original submissions of abbreviated applications for generic new animal drugs that were received by FDA before July 1, 2008, were not assessed fees (21 U.S.C. 379j-21(a)(1)(A)). Some of these non-fee-paying submissions were later resubmitted on or after July 1 because the initial submission was not approved by FDA (*i.e.,* FDA marked the submission as incomplete and requested additional non-administrative information) or because the original submission was withdrawn by the sponsor. Abbreviated applications for generic new animal drugs resubmitted on or after July 1, 2008, are subject to user fees. In this notice, FDA refers to these resubmitted applications as "reactivated" applications.

Also, under AGDUFA II, an abbreviated application for an animal generic drug subject to the criteria in section 512(d)(4) of the FD&C Act and submitted on or after October 1, 2013, shall be subject to 50 percent of the fee applicable to all other abbreviated applications for a generic new animal drug (21 U.S.C. 379j-21(a)(1)(C)(ii)).

Regarding original submissions of abbreviated applications for generic new animal drugs, FDA is assuming that the number of applications that will pay fees in FY 2017 will equal the average number of submissions over the 5 most recently completed years of the AGDUFA program (FY 2011–FY 2015). FDA believes that this is a reasonable approach after 7 complete years of experience with this program.

The average number of original submissions of abbreviated applications for generic new animal drugs over the 5 most recently completed years is 10 applications not subject to the criteria in section 512(d)(4) of the FD&C Act and 4.4 submissions subject to the criteria in section 512(d)(4). Each of the submissions described under section 512(d)(4) of the FD&C Act pays 50 percent of the fee paid by the other applications and will be counted as one half of a fee. Adding all of the applications not subject to the criteria in section 512(d)(4) of the FD&C Act and 50 percent of the number that are subject to such criteria results in a total of 12.2 anticipated full fees.

In prior years, FDA had estimated the number of reactivations of abbreviated applications for generic new animal drugs that had been originally submitted prior to July 1, 2008. Over the years, that number has decreased to the point that FDA no longer expects to receive any reactivations of applications initially submitted prior to July 1, 2008, and will include no provision for them in its fee estimates. Should such a submission be made, the submitter will be expected to pay the appropriate fee.

Based on the previous assumptions, FDA is estimating that it will receive a total of 12.2 fee-paying generic new animal drug applications in FY 2017 (10 original applications paying a full fee and 4.4 applications paying a half fee).

B. Application Fee Rates for FY 2017

FDA must set the fee rates for FY 2017 so that the estimated 12.2 abbreviated applications that pay the fee will generate a total of $2,835,000. To generate this amount, the fee for a generic new animal drug application, rounded to the nearest hundred dollars, will have to be $232,400, and for those applications that are subject to the criteria set forth in section 512(d)(4) of the FD&C Act, 50 percent of that amount, or $116,200.

IV. Generic New Animal Drug Product Fee Calculations for FY 2017

A. Product Fee Revenues and Numbers of Fee-Paying Products

The generic new animal drug product fee (also referred to as the product fee) must be paid annually by the person named as the applicant in an abbreviated application or supplemental abbreviated application for a generic new animal drug product submitted for listing under section 510 of the FD&C Act (21 U.S.C. 360), and who had an abbreviated application or supplemental abbreviated application for a generic new animal drug product pending at FDA after September 1, 2008 (see 21 U.S.C. 379j–21(a)(2)). The term "generic new animal drug product" means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an abbreviated application for a generic new animal drug or supplemental abbreviated application for a generic new animal drug has been approved (21 U.S.C. 379j–21(k)(6)). The product fees are to be set so that they will generate $4,253,000 in fee revenue for FY 2017.

To set generic new animal drug product fees to realize $4,253,000, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2017. FDA gathered data on all generic new animal drug products that have been submitted for listing under section 510 of the FD&C Act and matched this to the list of all persons who FDA estimated would have an abbreviated new animal drug application or supplemental abbreviated application pending after September 1, 2008. As of June 2016, FDA estimates a total of 417 products submitted for listing by persons who had an abbreviated application for a generic new animal drug or supplemental abbreviated application for a generic new animal drug pending after September 1, 2008. Based on this, FDA believes that a total of 417 products will be subject to this fee in FY 2017.

In estimating the fee revenue to be generated by generic new animal drug product fees in FY 2017, FDA is assuming that less than two products invoiced will qualify for minor use/minor species fee waiver (see 21 U.S.C. 379j–21(d)). FDA has kept this estimate at zero percent this year, based on historical data over the past 5 completed years of the AGDUFA program.

Accordingly, the Agency estimates that a total of 417 products will be subject to product fees in FY 2017.

B. Product Fee Rates for FY 2017

FDA must set the fee rates for FY 2017 so that the estimated 417 products that pay fees will generate a total of $4,253,000. To generate this amount will require the fee for a generic new animal drug product, rounded to the nearest $5, to be $10,200.

V. Generic New Animal Drug Sponsor Fee Calculations for FY 2017

A. Sponsor Fee Revenues and Numbers of Fee-Paying Sponsors

The generic new animal drug sponsor fee (also referred to as the sponsor fee) must be paid annually by each person who: (1) Is named as the applicant in an abbreviated application for a generic new animal drug, except for an approved application for which all subject products have been removed from listing under section 510 of the FD&C Act, or has submitted an investigational submission for a generic new animal drug that has not been terminated or otherwise rendered inactive and (2) had an abbreviated application for a generic new animal drug, supplemental abbreviated application for a generic new animal drug, or investigational submission for a generic new animal drug pending at FDA after September 1, 2008 (see 21 U.S.C. 379j–21(k)(7) and 379j–21(a)(3), respectively). A generic new animal drug sponsor is subject to only one such fee each fiscal year (see 21 U.S.C. 379j–21(a)(3)(C)). Applicants with more than six approved abbreviated applications will pay 100 percent of the sponsor fee; applicants with more than one and fewer than seven approved abbreviated applications will pay 75 percent of the sponsor fee; and applicants with one or fewer approved abbreviated applications will pay 50 percent of the sponsor fee (see 21 U.S.C. 379j–21(a)(3)(C)). The sponsor fees are to be set so that they will generate $4,253,000 in fee revenue for FY 2017.

To set generic new animal drug sponsor fees to realize $4,253,000, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2017. FDA now has 7 complete years of experience collecting these sponsor fees. Based on the number of firms that meet this definition and the average number of firms paying fees at each level over the 5 most recently completed years of the AGDUFA program (FY 2011 through FY 2015), FDA estimates that in FY 2017, 13 sponsors will pay 100 percent fees, 18 sponsors will pay 75 percent fees, and 38 sponsors will pay 50 percent fees. That totals the equivalent of 45.5 full sponsor fees (13 times 100 percent or 13, plus 18 times 75 percent or 13.5, plus 38 times 50 percent or 19).

FDA estimates that about 3 percent of all of these sponsors, or 1.37, may qualify for a minor use/minor species fee waiver (see 21 U.S.C. 379j–21(d)). FDA has reduced the estimate of the percentage of sponsors that will not pay fees from 4 percent to 3 percent this year, based on historical data over the past 5 completed years of the AGDUFA program.

Accordingly, the Agency estimates that the equivalent of 44.13 full sponsor fees (45.5 minus 1.37) are likely to be paid in FY 2017.

B. Sponsor Fee Rates for FY 2017

FDA must set the fee rates for FY 2017 so that the estimated equivalent of 44.13 full sponsor fees will generate a total of $4,253,000. To generate this amount will require the 100 percent fee for a generic new animal drug sponsor, rounded to the nearest $50, to be $96,350. Accordingly, the fee for those paying 75 percent of the full sponsor fee will be $72,263, and the fee for those paying 50 percent of the full sponsor fee will be $48,175.

VI. Fee Schedule for FY 2017

The fee rates for FY 2017 are summarized in table 2 of this document.

TABLE 2—FY 2017 FEE RATES

Generic new animal drug user fee category	Fee rate for FY 2017 ($)
Abbreviated Application Fee for Generic New Animal Drug except those subject to the criteria in section 512(d)(4)	$232,400
Abbreviated Application Fee for Generic New Animal Drug subject to the criteria in section 512(d)(4)	116,200
Generic New Animal Drug Product Fee	10,200
100 Percent Generic New Animal Drug Sponsor Fee[1]	96,350
75 Percent Generic New Animal Drug Sponsor Fee[1]	72,263
50 Percent Generic New Animal Drug Sponsor Fee[1]	48,175

[1] An animal drug sponsor is subject to only one fee each fiscal year.

VII. Procedures for Paying FY 2017 Generic New Animal Drug User Fees

A. Abbreviated Application Fees and Payment Instructions

The FY 2017 fee established in the new fee schedule must be paid for an abbreviated new animal drug application subject to fees under AGDUFA II that is submitted on or after October 1, 2016. Payment must be made in U.S. currency from a U.S. bank by check, bank draft, U.S. postal money order payable to the order of the Food and Drug Administration, wire transfer, or electronically using Pay.gov. The preferred payment method is online using electronic check (Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay or the Pay.gov payment option is available to you after you submit a cover sheet.* Once you search for your invoice, click "Pay Now" to be redirected to Pay.gov. Note that electronic payment options are based on the balance due. Payment by credit card is available for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be drawn on U.S bank accounts as well as U.S. credit cards.

On your check, bank draft, U.S. or postal money order, please write your application's unique Payment Identification Number, beginning with the letters "AG", from the upper right-hand corner of your completed Animal Generic Drug User Fee Cover Sheet. Also write the FDA post office box number (P.O. Box 979033) on the enclosed check, bank draft, or money order. Your payment and a copy of the completed Animal Generic Drug User Fee Cover Sheet can be mailed to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000.

If payment is made via wire transfer, send payment to U. S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Name: Food and Drug Administration, Account No.: 75060099, Routing No.: 021030004, Swift No.: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., 14th Floor, Silver Spring, MD 20993–0002. You are responsible for any administrative costs associated with the processing of a wire transfer. Contact your bank or financial institution about the fee and add it to your payment to ensure that your fee is fully paid.

If you prefer to send a check by a courier, the courier may deliver the check and printed copy of the cover sheet to: U.S. Bank, Attn: Government Lockbox 979033, 1005 Convention Plaza, St. Louis, MO 63101. (**Note:** This address is for courier delivery only. If you have any questions concerning courier delivery contact the U.S. Bank at 314–418–4013. This phone number is only for questions about courier delivery.)

The tax identification number of FDA is 53–0196965. (**Note:** In no case should the payment for the fee be submitted to FDA with the application.)

It is helpful if the fee arrives at the bank at least a day or two before the abbreviated application arrives at FDA's Center for Veterinary Medicine (CVM). FDA records the official abbreviated application receipt date as the later of the following: The date the application was received by CVM, or the date U.S. Bank notifies FDA that your payment in the full amount has been received, or when the U. S. Department of the Treasury notifies FDA of payment. U.S. Bank and the United States Treasury are required to notify FDA within 1 working day, using the Payment Identification Number described previously.

B. Application Cover Sheet Procedures

Step One—Create a user account and password. Log onto the AGDUFA Web site at *http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm137049.htm* and scroll down the page until you find the link "Create AGDUFA User Fee Cover Sheet." Click on that link and follow the directions. For security reasons, each firm submitting an application will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process.

Step Two—Create an Animal Generic Drug User Fee Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your user name and password, complete the steps required to create an Animal Generic Drug User Fee Cover Sheet. One cover sheet is needed for each abbreviated animal drug application. Once you are satisfied that the data on the cover sheet is accurate and you have finalized the cover sheet, you will be able to transmit it electronically to FDA and you will be able to print a copy of your cover sheet showing your unique Payment Identification Number.

Step Three—Send the payment for your application as described in Section VII.A of this document.

Step Four—Please submit your application and a copy of the completed Animal Generic Drug User Fee Cover Sheet to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV–199), 7500 Standish Pl., Rockville, MD 20855.

C. Product and Sponsor Fees

By December 31, 2016, FDA will issue invoices and payment instructions for product and sponsor fees for FY 2017 using this fee schedule. Fees will be due by January 31, 2017. FDA will issue invoices in November 2017 for any products and sponsors subject to fees for FY 2017 that qualify for fees after the December 2016 billing.

Dated: July 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–17811 Filed 7–27–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1502]

Blood Donor Deferral Policy for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is establishing a public docket for comment on the Agency's blood donor deferral recommendations for reducing the risk of human immunodeficiency virus (HIV) transmission as described in the document entitled "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry" dated December 2015. Interested persons are invited to submit comments, supported by scientific evidence such as data from research, regarding potential blood donor deferral policy options to reduce the risk of HIV transmission, including the feasibility of moving from the existing time-based deferrals related to risk behaviors to alternate deferral options, such as the use of individual risk assessments. Additionally, comments are invited regarding the design of potential studies to evaluate the feasibility and effectiveness of such alternative deferral options. FDA will take the comments received into account as it continues to reevaluate and update blood donor deferral policies as new scientific information becomes available.

DATES: Submit either electronic or written comments by November 25, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2016–N–1502 for "Blood Donor Deferral Policy for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Establishment of Public Docket; Request for Comments." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jonathan McKnight, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 23, 2015 (80 FR 79913), FDA announced the availability of the guidance entitled "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry" dated December 2015 (December 2015 guidance) *http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM446580.pdf.*

The December 2015 guidance updates blood donor deferral recommendations to reflect the most current scientific evidence. The recommendations also help ensure continued safety of the blood supply by reducing the risk of HIV transmission by blood and blood products. As part of the updated blood donor deferral recommendations in the December 2015 guidance, FDA changed the recommendation for an indefinite deferral period for men who have sex with men (MSM) to a deferral period of 12 months since the last sexual contact with another man. The updated recommendations better align the deferral period for MSM with the deferral period for other men and women at increased risk for HIV infection, such as those who had a recent blood transfusion or who have been accidentally exposed to the blood of another individual through a needle stick. In reviewing the Agency's recommendations to reduce the risk of HIV transmission through blood and blood products, FDA rigorously examined several alternative options, including individual risk assessment. Ultimately, FDA concluded that the 12-month deferral period is supported by the best available scientific evidence, at this point in time, relevant to the U.S. population.

As described in the December 2015 guidance, throughout the process of comprehensively updating blood donor deferral policies, FDA has worked with other government Agencies, considered input from external advisory committees, reviewed comments from stakeholders to the draft guidance of the same title (80 FR 27973, May 15, 2015), and carefully examined the most recent available scientific evidence. FDA also has implemented a nationally representative transfusion-transmissible infections monitoring system for the U.S. blood supply with assistance from the National Heart, Lung, and Blood Institute at the National Institutes of Health. This system provides critical information to help inform future actions that FDA may take on blood donor policies.

When FDA issued the December 2015 guidance, it noted that while the December 2015 guidance represents FDA's current thinking on the subject, FDA was committed to continuing to reevaluate and update blood donor deferral policies as new scientific information becomes available. FDA also noted that, because the process must be data-driven, FDA could not specify a time for when future policy changes might occur.

As part of the effort to continue to assess its donor deferral policies, FDA is opening this docket to provide a mechanism for the public to submit additional information regarding potential blood donor deferral policy options. Specifically, we invite interested persons to submit to the docket comments supported by scientific evidence regarding possible revisions to FDA's blood donor deferral policies to reduce the risk of HIV transmission by blood and blood products. FDA requests that commenters provide scientific evidence, such as data from research, to support any suggestions. Additionally, comments are invited regarding the design of potential studies to evaluate the feasibility or effectiveness of such alternative deferral policy options.

FDA recognizes that many stakeholders have expressed the desire to move from a time-based deferral period to a deferral policy based on individual risk assessment. An individual risk assessment would involve asking potential donors a series of questions designed to defer donors with high risk behaviors. In particular, we invite commenters to address the following and provide supporting scientific evidence such as data from research:

1. What questions would most effectively identify individuals at risk of transmitting HIV through blood donation?
2. Are there specific questions that could be asked that might best capture the recent risk of a donor acquiring HIV infection, such as within the 2 to 4 weeks immediately preceding blood donation?
3. How specific can the questions be regarding sexual practices while remaining understandable and acceptable to all blood donors? For example, could questions about specific sexual behaviors be asked if they helped to identify which donors should be at least temporarily deferred because of risk factors? To the extent the questions are explicit about sexual practices, how willing will donors be to answer such questions accurately?
4. Under what circumstances would a short deferral period for high risk behavior be appropriate? For each short deferral period identified, please specify the duration of the deferral and provide the scientific rationale.
5. What changes might be necessary within blood collection establishments to assure that accurate, individual HIV risk assessments are performed?
6. How best to design a potential study to evaluate the feasibility and effectiveness of alternative deferral options such as individual risk assessment?

FDA will consider comments and supporting scientific data received as it continues to reevaluate and update blood donor deferral policies as new scientific information becomes available.

Dated: July 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–17804 Filed 7–26–16; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0007]

Prescription Drug User Fee Rates for Fiscal Year 2017

AGENCY: Food and Drug Administration, HHS

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for prescription drug user fees for fiscal year (FY) 2017. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Prescription Drug User Fee Amendments of 2012 (PDUFA V), authorizes FDA to collect user fees for certain applications for the review of human drug and biological products, on establishments where the products are made, and on such products. This notice establishes the fee rates for FY 2017.

FOR FURTHER INFORMATION CONTACT: Robert J. Marcarelli, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE–14202F, Silver Spring, MD 20993–0002, 301–796–7223.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 735 and 736 of the FD&C Act (21 U.S.C. 379g and 379h, respectively) establish three different kinds of user fees. Fees are assessed on the following: (1) Certain types of applications and supplements for the review of human drug and biological products; (2) certain establishments where such products are made; and (3) certain products (section 736(a) of the FD&C Act). When certain conditions are met, FDA may waive or reduce fees (section 736(d) of the FD&C Act).

For FY 2013 through FY 2017, the base revenue amounts for the total revenues from all PDUFA fees are established by PDUFA V. The base revenue amount for FY 2013, which became the base amount for the remaining four FYs of PDUFA V, is $718,669,000, as published in the **Federal Register** of August 1, 2012 (77 FR 45639). The FY 2013 base revenue amount is further adjusted each year after FY 2013 for inflation and workload. For FY 2017, fee revenue and fees may be further adjusted by the final year adjustment. In addition, for FY 2017, excess collections are offset as required by the FD&C Act. Fees for applications, establishments, and products are to be established each year by FDA so that revenues from each category will provide one-third of the total revenue to be collected each year.

This document provides fee rates for FY 2017 for an application requiring clinical data ($2,038,100), for an application not requiring clinical data or a supplement requiring clinical data ($1,019,050), for an establishment ($512,200), and for a product ($97,750). These fees are effective on October 1, 2016, and will remain in effect through September 30, 2017. For applications and supplements that are submitted on or after October 1, 2016, the new fee schedule must be used. Invoices for establishment and product fees for FY 2017 will be issued in August 2016 using the new fee schedule.

II. Fee Revenue Amount for FY 2017

The base revenue amount for FY 2017 is $718,669,000 prior to adjustments for inflation, workload, the offset of excess collections, and the final year adjustment (see sections 736(c)(1), 736(c)(2), 736(g)(4), and 736(c)(3) of the FD&C Act, respectively).

A. FY 2017 Statutory Fee Revenue Adjustments for Inflation

PDUFA V specifies that the $718,669,000 is to be further adjusted for inflation increases for FY 2017 using two separate adjustments—one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see section 736(c)(1) of the FD&C Act).

The component of the inflation adjustment for payroll costs shall be one plus the average annual percent change in the cost of all PC&B paid per full-time equivalent (FTE) position at FDA for the first three of the preceding four FYs, multiplied by the proportion of PC&B costs to total FDA costs of process for the review of human drug applications for the first three of the preceding four FYs (see section 736(c)(1)(A) and (c)(1)(B) of the FD&C Act).

Table 1 summarizes that actual cost and FTE data for the specified FYs, and provides the percent changes from the previous FYs and the average percent changes over the first three of the four FYs preceding FY 2017. The 3-year average is 1.8759 percent.

TABLE 1—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGES

Fiscal year	2013	2014	2015	3-year average
Total PC&B	$1,927,703,000	$2,054,937,000	$2,232,304,000	
Total FTE	13,974	14,555	15,484	
PC&B per FTE	$137,949	$141,184	$144,168	
Percent Change From Previous Year	1.1690	2.3451	2.1136	1.8759

The statute specifies that this 1.8759 percent should be multiplied by the proportion of PC&B costs to total FDA costs of the process for the review of human drug applications. Table 2 shows the PC&B and the total obligations for the process for the review of human drug applications for three FYs.

TABLE 2—PC&B AS A PERCENT OF FEE REVENUES SPENT ON THE PROCESS FOR THE REVIEW OF HUMAN DRUG APPLICATIONS

Fiscal year	2013	2014	2015	3-year average
Total PC&B	$568,206,210	$585,260,720	$615,483,892	
Total Costs	$966,169,007	$1,077,263,695	$1,127,664,528	
PC&B Percent	58.8102	54.3285	54.5804	55.9064

The payroll adjustment is 1.8759 percent from table 1 multiplied by 55.9064 percent (or 1.0487 percent).

The statute specifies that the portion of the inflation adjustment for non-payroll costs is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Baltimore, DC–MD–VA–WV; not seasonally adjusted; all items; annual index) for the first three years of the preceding four years of available data multiplied by the proportion of all costs other than PC&B costs to total costs of the process for the review of human drug applications for the first three years of the preceding four FYs (see section 736(c)(1)(C) of the FD&C Act). Table 3 provides the summary data for the percent changes in the specified CPI for the Washington-Baltimore area. The data are published by the Bureau of Labor Statistics and can be found on its Web site at: *http://data.bls.gov/cgi-bin/surveymost?cu*. The data can be viewed by checking the box marked "Washington-Baltimore All Items, November 1996=100—CUURA311SA0" and then selecting "Retrieve Data".

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN CPI FOR WASHINGTON-BALTIMORE AREA

Year	2013	2014	2015	3-year average
Annual CPI	152.500	154.847	155.353	
Annual Percent Change	1.5232	1.5390	0.3268	1.1297

To calculate the inflation adjustment for non-payroll costs, we multiply the 1.1297 percent by the proportion of all costs other than PC&B to total costs of the process for the review of human drug applications obligated. Since 55.9064 percent was obligated for PC&B as shown in Table 2, 44.0936 percent is the portion of costs other than PC&B (100 percent minus 55.9064 percent equals 44.0936 percent). The non-payroll adjustment is 1.1297 percent times 44.0936 percent, or 0.4981 percent.

Next, we add the payroll adjustment (1.0487 percent) to the non-payroll adjustment (0.4981 percent), for a total inflation adjustment of 1.5468 percent (rounded) for FY 2017.

PDUFA V provides for this inflation adjustment to be compounded after FY 2013 (see section 736(c)(1) of the FD&C Act). This factor for FY 2017 (1.5468 percent) is compounded by adding one and then multiplying by one plus the compound inflation adjustment factor for FY 2016 (6.4414 percent), as published in the **Federal Register** of August 3, 2015 (80 FR 46028 at 46032), which equals to 1.080878 (rounded) (1.015468 × 1.064414) for FY 2017. We then multiply the base revenue amount for FY 2017 ($718,669,000) by 1.080878, yielding an inflation-adjusted amount of $776,793,511.

B. FY 2017 Statutory Fee Revenue Adjustments for Workload

The statute specifies that after the $718,669,000 has been adjusted for inflation, the inflation-adjusted amount shall be further adjusted for workload (see section 736(c)(2) of the FD&C Act).

To calculate the FY 2017 workload adjustment, FDA calculated the average number of each of the four types of applications specified in the workload adjustment provision: (1) Human drug applications; (2) active commercial investigational new drug applications (INDs) (applications that have at least one submission during the previous 12 months); (3) efficacy supplements; and (4) manufacturing supplements received over the 3-year period that ended on June 30, 2012 (base years), and the average number of each of these types of applications over the most recent 3-year period that ended June 30, 2016.

The calculations are summarized in table 4. The 3-year averages for each application category are provided in column 1 ("3-Year Average Base Years 2010–2012") and column 2 ("3-Year Average 2014–2016"). Column 3 reflects the percent change in workload from column 1 to column 2. Column 4 shows the weighting factor for each type of application, estimating how much of the total FDA drug review workload was accounted for by each type of application in the table during the most recent 3 years. Column 5 is the weighted percent change in each category of workload. This was derived by multiplying the weighting factor in each line in column 4 by the percent change from the base years in column 3. The values in column 5 are summed, reflecting an increase in workload of 13.1047 percent (rounded) for FY 2017 when compared to the base years.

TABLE 4—WORKLOAD ADJUSTER CALCULATION FOR FY 2017

Application type	Column 1	Column 2	Column 3	Column 4	Column 5
	3-year average base years 2010–2012	3-year average 2014–2016	Percent change (column 1 to column 2)	Weighting factor (percent)	Weighted percent change
New Drug Applications/Biologics License Applications	124.3000	147.3000	18.5036	35.8514	6.6338
Active Commercial INDs	6830.0000	7598.0000	11.2445	41.0966	4.6211
Efficacy Supplements	136.3000	196.3000	44.0205	6.8122	2.9988
Manufacturing Supplements	2548.3000	2368.0000	−7.0753	16.2399	−1.1490
FY 2017 Workload Adjuster					13.1047

Table 5 shows the calculation of the inflation and workload adjusted amount for FY 2017. The $718,669,000 subject to adjustment on line 1 is multiplied by the inflation adjustment factor of 1.080878, resulting in the inflation-adjusted amount on line 3, $776,793,511. That amount is then multiplied by one plus the workload adjustment of 13.1047 percent on line 4, resulting in the inflation and workload adjusted amount of $878,590,000 on line 5, rounded to the nearest thousand dollars.

TABLE 5—PDUFA INFLATION AND WORKLOAD ADJUSTED AMOUNT FOR FY 2017, SUMMARY CALCULATION

FY 2013 Revenue Amount and Base Subsequent FYs as published in the **Federal Register** of August 1, 2012 (77 FR 45639) (rounded to nearest thousand dollars).	$718,669,000	Line 1.
Inflation Adjustment Factor for FY 2017 (1 plus 8.0878 percent)	1.080878	Line 2.
Inflation Adjusted Amount	$776,793,511	Line 3.
Workload Adjustment Factor for FY 2017 (1 plus 13.1047 percent)	1.131047	Line 4.
Inflation and Workload Adjusted Amount (rounded to nearest thousand dollars)	$878,590,000	Line 5.

III. Offset for Excess Collections Through FY 2016

Under the provisions of the FD&C Act, if the sum of the cumulative amount of the fees collected for FY 2013 through 2015, and the amount of fees estimated to be collected under this section for FY 2016, exceeds the cumulative amount appropriated for fees for FYs 2013 through 2016, the excess shall be credited to FDA's appropriation account and subtracted from the amount of fees that FDA would otherwise be authorized to collect for FY 2017 under the FD&C Act (see section 736(g)(4) of the FD&C Act as amended by PDUFA V).

Table 6 shows the amounts specified in appropriation acts for each year from FY 2013 through FY 2016, and the amounts FDA has collected for FYs 2013, 2014, and 2015 as of June 30, 2016, and an additional $70,907,000 (rounded to the nearest thousand dollars) that FDA estimates it will collect in FY 2016 based on historical data. Table 6 shows the estimated cumulative difference between PDUFA fee amounts specified in appropriation acts for FY 2013 through FY 2016 and PDUFA fee amounts collected.

TABLE 6—OFFSETS TO BE TAKEN FOR PDUFA V

Fiscal year	Collections realized ($)	Collection amount specified in appropriation acts ($)	Amount in excess of collection amount specified in appropriation acts ($)
2013	721,224,494	718,669,000	2,555,494
2014	805,856,366	760,000,000	45,856,366
2015	852,746,867	798,000,000	54,746,867
2016	872,388,000	851,481,000	20,907,000
Net Balance to be Offset When Fees are Set for FY 2017			124,065,726

Note: FY 2016 'Collections Realized' is the amount FDA estimates it will collect in FY 2016 based on historical data.

The cumulative fees collected for FYs 2013 through 2016 are estimated to be $124,065,726 greater than the cumulative fee amounts specified in appropriation acts during this same period. Reducing the inflation and workload adjusted amount of $878,590,000 by the PDUFA V offset of $124,066,000 (rounded to the nearest thousand dollars) results in an amount of $754,524,000, before the final year adjustment.

IV. Final Year Adjustment

Under the provisions of the FD&C Act, as amended, for FY 2017 the Secretary of Health and Human Services may, in addition to the inflation and workload adjustments, further increase the fees and fee revenues if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for the process for the review of human drug applications for the first 3 months of FY 2018. If such an adjustment is necessary, the rationale for the amount of this increase shall be contained in the annual notice establishing fee revenues and fees for FY 2017 (see section 736(c)(3) of the FD&C Act).

After running analyses on the status of PDUFA's operating reserves and its estimated balance as of the beginning of FY 2018, FDA estimates that the PDUFA program will have sufficient funds for the operating reserves, thus FDA will not be performing a final year adjustment for FY 2018 because FDA has determined such an adjustment to be unnecessary.

The FD&C Act specifies that one-third of the total fee revenue is to be derived from application fees, one-third from establishment fees, and one-third from product fees (see section 736(b)(2) of the FD&C Act). Accordingly, one-third of the total revenue amount ($754,524,000), or a total of $251,508,000, is the amount of fee revenue that will be derived from each fee type: Application fees, establishment fees, and product fees.

V. Application Fee Calculations

A. Application Fee Revenues and Application Fees

Application fees will be set to generate one-third of the total fee revenue amount, or $251,508,000 in FY 2017.

B. Estimate of the Number of Fee-Paying Applications and Setting the Application Fees

For FY 2013 through FY 2017, FDA will estimate the total number of fee-paying full application equivalents (FAEs) it expects to receive the next FY by averaging the number of fee-paying FAEs received in the three most recently completed FYs. Beginning with FY 2016, prior year FAE totals will be updated annually to reflect refunds and waivers processed after the close of the FY.

In estimating the number of fee-paying FAEs, a full application requiring clinical data counts as one FAE. An application not requiring clinical data counts as one-half of an FAE, as does a supplement requiring clinical data. An application that is withdrawn, or refused for filing, counts as one-fourth of an FAE if the applicant initially paid a full application fee, or one-eighth of an FAE if the applicant initially paid one-half of the full application fee amount.

As Table 7 shows, the average number of fee-paying FAEs received annually in the most recent 3-year period is 123.405 FAEs. FDA will set fees for FY 2017 based on this estimate as the number of full application equivalents that will pay fees.

TABLE 7—FEE-PAYING FAES

FY	2013	2014	2015	3-year average
Fee-Paying FAEs	109.010	128.750	132.456	123.405

Note: Beginning with FY 2016, prior year FAE totals will be updated annually to reflect refunds and waivers processed after the close of the FY.

The FY 2017 application fee is estimated by dividing the average number of full applications that paid fees over the latest 3 years, 123.405, into the fee revenue amount to be derived from application fees in FY 2017, $251,508,000. The result, rounded to the nearest hundred dollars, is a fee of $2,038,100 per full application requiring clinical data, and $1,019,050 per application not requiring clinical data or per supplement requiring clinical data.

VI. Fee Calculations for Establishment and Product Fees

A. Establishment Fees

At the beginning of FY 2016, the establishment fee was based on an estimate that 485 establishments would be subject to and would pay fees. By the end of FY 2016, FDA estimates that 523 establishments will have been billed for establishment fees, before all decisions on requests for waivers or reductions are made. FDA estimates that a total of 16 establishment fee waivers or reductions will be made for FY 2016. In addition, FDA estimates that another 16 full establishment fees will be exempted this year based on the orphan drug exemption in section 736(k) of the FD&C Act. Subtracting 32 establishments (16 waivers, plus the estimated 16 establishments under the orphan exemption) from 523 leaves a net of 491 fee-paying establishments. FDA will use 491 to estimate the FY 2017 establishments paying fees. The fee per establishment is determined by dividing the adjusted total fee revenue to be derived from establishments ($251,508,000) by the estimated 491 establishments, for an establishment fee rate for FY 2017 of $512,200 (rounded to the nearest hundred dollars).

B. Product Fees

At the beginning of FY 2016, the product fee was based on an estimate that 2,480 products would be subject to and would pay product fees. By the end of FY 2016, FDA estimates that 2,646 products will have been billed for product fees, before all decisions on requests for waivers, reductions, or exemptions are made. FDA assumes that there will be 41 waivers and reductions granted. In addition, FDA estimates that another 32 product fees will be exempted this year based on the orphan drug exemption in section 736(k) of the FD&C Act. FDA estimates that 2,573 products will qualify for and pay product fees in FY 2016, after allowing for an estimated 73 waivers and reductions, including the orphan drug products, and will use this number for its FY 2017 estimate. The FY 2017 product fee rate is determined by dividing the adjusted total fee revenue to be derived from product fees ($251,508,000) by the estimated 2,573 products for a FY 2017 product fee of $97,750 (rounded to the nearest ten dollars).

VII. Fee Schedule for FY 2017

The fee rates for FY 2017 are displayed in table 8:

TABLE 8—FEE SCHEDULE FOR FY 2017

Fee category	Fee rates for FY 2017 ($)
Applications:	
Requiring clinical data	2,038,100
Not requiring clinical data	1,019,050
Supplements requiring clinical data	1,019,050
Establishments	512,200
Products	97,750

VIII. Fee Payment Options and Procedures

A. Application Fees

The appropriate application fee established in the new fee schedule must be paid for any application or supplement subject to fees under PDUFA that is received on or after October 1, 2016. Payment must be made in U.S. currency by electronic check, check, bank draft, wire transfer, or U.S. postal money order payable to the order of the Food and Drug Administration. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay.* Once you search for your invoice, click "Pay Now" to be redirected to Pay.gov. Note that electronic payment options are based on the balance due. Payment by credit card is available for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be drawn on U.S bank accounts as well as U.S. credit cards.

FDA has partnered with the U.S. Department of the Treasury to use Pay.gov, a Web-based payment application, for online electronic payment. The Pay.gov feature is available on the FDA Web site after the user fee ID number is generated.

Please include the user fee identification (ID) number on your check, bank draft, or postal money order. Your payment can be mailed to: Food and Drug Administration, P.O. Box 979107, St. Louis, MO 63197–9000.

If checks are to be sent by a courier that requests a street address, the courier can deliver the checks to: U.S. Bank, Attention: Government Lockbox 979107, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery contact the U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery).

Please make sure that the FDA post office box number (P.O. Box 979107) is written on the check, bank draft, or postal money order.

If paying by wire transfer, please reference your unique user fee ID number when completing your transfer. The originating financial institution may charge a wire transfer fee. Please ask your financial institution about the fee and add it to your payment to ensure that your fee is fully paid. The account information for wire transfers is as follows: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., 14th Floor, Silver Spring, MD 20993–0002.

The tax identification number of FDA is 53–0196965.

B. Establishment and Product Fees

FDA will issue invoices for establishment and product fees for FY 2017 under the new fee schedule in August 2016. Payment will be due on October 1, 2016. FDA will issue invoices in November 2017 for any products and establishments subject to fees for FY 2017 that qualify for fee assessments after the August 2016 billing.

Dated: July 25, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–17870 Filed 7–27–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0530]

Agency Information Collection Activities; Proposed Collection; Comment Request; Pre-Submission Program for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of

information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requests for feedback submitted under the Pre-Submission program for medical devices.

DATES: Submit either electronic or written comments on the collection of information by September 26, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2012–D–0530 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Pre-Submission Program for Medical Devices." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20851, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Pre-Submission Program for Medical Devices—OMB Control Number 0910–0756—Extension

The guidance entitled "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff" describes the Pre-Submission program for medical devices reviewed in the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER). The guidance provides recommendations regarding the information that should be submitted in a Pre-Submission package and procedures that should be followed for meetings between CDRH and CBER staff and industry representatives or application sponsors. In addition to Pre-Submissions, the guidance addresses other feedback mechanisms including Informational Meetings, Study Risk Determinations, Formal Early Collaboration Meetings, and Submission Issue Meetings and the procedures to request feedback using these mechanisms.

A Pre-Submission is defined as a formal written request from an applicant for feedback from FDA to be provided in the form of a formal written response or, if the manufacturer chooses, a meeting or teleconference in which the feedback is documented in meeting minutes. A Pre-Submission is appropriate when FDA's feedback on specific questions is necessary to guide product development and/or application preparation. The proposed collections of information are necessary to allow the Agency to receive Pre-Submission packages in order to implement this voluntary submission program.

For clarity, we are requesting that the title of the information collection request, OMB control number 0910–0756, be changed to "Pre-Submission Program for Medical Devices."

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA Center	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
CDRH	2,465	1	2,465	137	337,705
CBER	79	1	79	137	10,823
Total					348,528

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents are medical device manufacturers subject to FDA's laws and regulations. FDA's annual estimate of 2,544 submissions is based on experienced trends over the past several years. FDA's administrative and technical staffs, who are familiar with the requirements for current Pre-Submissions, estimate that an average of 137 hours is required to prepare a Pre-Submission.

Dated: July 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–17802 Filed 7–27–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee. The general function of the committees is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on September 14, 2016, from 8 a.m. to 5 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *PDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The committees will discuss a completed postmarketing-requirement randomized, placebo controlled trial of the neuropsychiatric effects of CHANTIX (varenicline), ZYBAN (bupropion), and nicotine replacement therapy, along with relevant published observational studies to determine whether the findings support changes to product labeling.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. Written submissions may be made to the contact person on or before August 30, 2016. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 22, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 23, 2016.

Persons attending FDA's advisory committee meetings are advised that the

Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Kalyani Bhatt at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 25, 2016.

Janice M. Soreth,

Acting Associate Commissioner, Special Medical Programs.

[FR Doc. 2016–17864 Filed 7–27–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Oncologic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on September 14, 2016, from 8 a.m. to 1 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Lauren D. Tesh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, *ODAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The committee will discuss new drug application 208714, apaziquone for intravesical instillation, application submitted by Spectrum Pharmaceuticals, Inc. The proposed indication (use) for this product is for immediate intravesical instillation post-transurethral resection of bladder tumors in patients with non-muscle invasive bladder cancer.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before August 30, 2016. Oral presentations from the public will be scheduled between approximately 10:45 a.m. and 11:45 a.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 22, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 23, 2016.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require special accommodations due to a disability, please contact Lauren D. Tesh at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 25, 2016.

Janice M. Soreth,

Acting Associate Commissioner, Special Medical Programs.

[FR Doc. 2016–17865 Filed 7–27–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0007]

Biosimilar User Fee Rates for Fiscal Year 2017

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for biosimilar user fees for fiscal year (FY) 2017. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Biosimilar User Fee Act of 2012 (BsUFA), authorizes FDA to assess and collect user fees for certain activities in connection with biosimilar biological product development, certain applications and supplements for

approval of biosimilar biological products, establishments where approved biosimilar biological products are made, and a biosimilar biological product fee for each biosimilar biological product approved in a biosimilar biological product application.

BsUFA directs FDA to establish, before the beginning of each fiscal year, the initial and annual biosimilar biological product development (BPD) fees, the reactivation fee, and the biosimilar biological product application, establishment, and product fees. These fees are effective on October 1, 2016, and will remain in effect through September 30, 2017.

FOR FURTHER INFORMATION CONTACT: David Haas, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE–14202I, Silver Spring, MD 20993–0002, 240–402–9845.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 744G, 744H, and 744I of the FD&C Act (21 U.S.C. 379j–51, 379j–52, and 379j–53), as added by BsUFA (Title IV of the Food and Drug Administration Safety and Innovation Act, Pub. L. 112–144), establish fees for biosimilar biological products. Under section 744H(a)(1)(A) of the FD&C Act, the initial BPD fee for a product is due when the sponsor submits an investigational new drug (IND) application that FDA determines is intended to support a biosimilar biological product application or within 5 calendar days after FDA grants the first BPD meeting, whichever occurs first. A sponsor who has paid the initial BPD fee is considered to be participating in FDA's BPD program for that product.

Under section 744H(a)(1)(B) of the FD&C Act, once a sponsor has paid the initial BPD fee for a product, the annual BPD fee is assessed beginning with the next fiscal year. The annual BPD fee is assessed for the product each fiscal year until the sponsor submits a marketing application for the product that is accepted for filing, or discontinues participation in FDA's BPD program.

Under section 744H(a)(1)(D) of the FD&C Act, if a sponsor has discontinued participation in FDA's BPD program and wants to re-engage with FDA on development of the product, the sponsor must pay a reactivation fee to resume participation in the program. The sponsor must pay the reactivation fee by the earlier of the following dates: No later than 5 calendar days after FDA grants the sponsor's request for a BPD meeting for that product, or upon the date of submission of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application. The sponsor will be assessed an annual BPD fee beginning with the first fiscal year after payment of the reactivation fee.

BsUFA also establishes fees for certain applications and supplements, establishments where approved biosimilar biological products are made in final dosage form, and for each biosimilar biological product approved in a biosimilar biological product application (section 744H(a)(2), 744H(a)(3), and 744H(a)(4), respectively, of the FD&C Act). Under certain conditions, FDA may grant a small business a waiver from its first biosimilar biological product application fee (section 744H(c)(1) of the FD&C Act).

Under BsUFA, the initial and annual BPD fee rates for a fiscal year are equal to 10 percent of the fee rate established under the Prescription Drug User Fee Act (PDUFA) for an application requiring clinical data for that fiscal year. The reactivation fee is equal to 20 percent of the fee rate established under PDUFA for an application requiring clinical data for that fiscal year. Finally, the application, establishment, and product fee rates under BsUFA are equal to the application, establishment, and product fee rates under PDUFA, respectively (section 744H(b)(1) of the FD&C Act).

II. Fee Amounts for FY 2017

BsUFA directs FDA to establish the biosimilar biological product fee rates in each fiscal year by reference to the user fees established under PDUFA for that fiscal year. For more information about BsUFA, please refer to the FDA Web site at *http://www.fda.gov/bsufa*. The BsUFA fee calculations for FY 2017 are described in this document.

A. Initial and Annual BPD Fees, Reactivation Fees

Under BsUFA, the initial and annual BPD fees equal 10 percent of the PDUFA fee for an application requiring clinical data, and the reactivation fee equals 20 percent of the PDUFA fee for an application requiring clinical data. The FY 2017 fee for an application requiring clinical data under PDUFA is $2,038,100. Multiplying the PDUFA application fee, $2,038,100, by 0.1 results in FY 2017 initial and annual BPD fees of $203,810. Multiplying the PDUFA application fee, $2,038,100, by 0.2 results in a FY 2017 reactivation fee of $407,620.

B. Application and Supplement Fees

The FY 2017 fee for a biosimilar biological product application requiring clinical data equals the PDUFA fee for an application requiring clinical data, $2,038,100. The FY 2017 fee for a biosimilar biological product application not requiring clinical data equals half this amount, $1,019,050. However, under section 744H(a)(2)(A) of the FD&C Act, if a sponsor submitting a biosimilar biological product application has previously paid an initial BPD fee, annual BPD fee(s), and/or reactivation fee(s) for the product that is the subject of the application, the fee for the application is reduced by the cumulative amount of these previously paid fees. The FY 2017 fee for a biosimilar biological product supplement with clinical data is $1,019,050, which is half the fee for a biosimilar biological product application requiring clinical data.

C. Establishment Fee

The FY 2017 biosimilar biological product establishment fee for establishments where approved biosimilar biological products are made is equal to the FY 2017 PDUFA establishment fee of $512,200.

D. Product Fee

The FY 2017 biosimilar biological product fee for each biosimilar biological product approved in a biosimilar biological product application is equal to the FY 2017 PDUFA product fee of $97,750.

III. Fee Schedule for FY 2017

The fee rates for FY 2017 are provided in table 1.

TABLE 1—FEE SCHEDULE FOR FY 2017

Fee category	Fee rates for FY 2017 ($)
Initial BPD	203,810
Annual BPD	203,810
Reactivation	407,620
Applications[1]	
Requiring clinical data	2,038,100
Not requiring clinical data	1,019,050
Supplement requiring clinical data	1,019,050
Establishment	512,200
Product	97,750

[1] Under section 744H(a)(2)(A) of the FD&C Act, if a sponsor that submits a biosimilar biological product application has previously paid an initial BPD fee, annual BPD fees, and/or reactivation fees for the product that is the subject of the application, the fee for the application is reduced by the cumulative amount of these previously paid fees.

IV. Fee Payment Options and Procedures

A. Initial BPD, Reactivation, Application, and Supplement Fees

The fees established in the new fee schedule are effective October 1, 2016. The initial BPD fee for a product is due when the sponsor submits an IND that FDA determines is intended to support a biosimilar biological product application for the product or within 5 calendar days after FDA grants the first BPD meeting for the product, whichever occurs first. Sponsors who have discontinued participation in the BPD program must pay the reactivation fee by the earlier of the following dates: No later than 5 calendar days after FDA grants the sponsor's request for a BPD meeting for that product, or upon the date of submission of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application.

The application or supplement fee for a biosimilar biological product is due upon submission of the application or supplement.

To make a payment of the initial BPD, reactivation, supplement, or application fee, complete the Biosimilar User Fee Cover Sheet, available on FDA's Web site (*http://www.fda.gov/bsufa*) and generate a user fee identification (ID) number. Payment must be made in U.S. currency by electronic check, check, bank draft, U.S. postal money order, or wire transfer. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay*. Once you search for your invoice, click "Pay Now" to be redirected to Pay.gov. Note that electronic payment options are based on the balance due. Payment by credit card is available for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be drawn on U.S bank accounts as well as U.S. credit cards.

FDA has partnered with the U.S. Department of the Treasury to use *http://www.pay.gov*, a Web-based payment application, for online electronic payment. The Pay.gov feature is available on FDA's Web site after completing the Biosimilar User Fee Cover Sheet and generating the user fee ID number.

Please include the user fee ID number on your check, bank draft, or postal money order, and make it payable to the Food and Drug Administration. Your payment can be mailed to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197–9000. If you prefer to send a check by a courier such as Federal Express or United Parcel Service, the courier may deliver the check and printed copy of the cover sheet to: U.S. Bank, ATTN: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only. Contact U.S. Bank at 314–418–4013 if you have any questions concerning courier delivery.) Please make sure that the FDA post office box number (P.O. Box 979108) is written on the check, bank draft, or postal money order.

If paying by wire transfer, please reference your unique user fee ID number when completing your transfer. The originating financial institution may charge a wire transfer fee. Please ask your financial institution about the fee and include it with your payment to ensure that your fee is fully paid. The account information is as follows: U.S. Department of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., 14th Floor, Silver Spring, MD 20993–0002.

The tax identification number of FDA is 53–0196965.

B. Annual BPD, Establishment, and Product Fees

FDA will issue invoices for annual BPD, biosimilar biological product establishment, and biosimilar biological product fees under the new fee schedule in August 2016. Payment instructions will be included in the invoices. Payment will be due on October 1, 2016. If sponsors join the BPD program after the annual BPD invoices have been issued in August 2016, FDA will issue invoices in November 2016 to firms subject to fees for FY 2017 that qualify for the annual BPD fee after the August 2016 billing. FDA will issue invoices in November 2017 for any annual products and establishments subject to fees for FY 2017 that qualify for fee assessments after the August 2016 billing.

Dated: July 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–17800 Filed 7–27–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI SPORE Review Meeting.

Date: October 7, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Rockville, 1750 Rockville Pike, Rockville, MD 20892.

Contact Person: Majed M. Hamawy, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W120, Rockville, MD 20892–9750, 240–276–6457, *mh101v@nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Program Project Review III (P01).

Date: October 13–14, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Klaus B. Piontek, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W612, Rockville, MD 20892–9750, 240–276–5413, *klaus.piontek@nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; Questions in Cancer Systems Biology.

Date: October 13, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Caterina Bianco, MD, Ph.D., Scientific Review Officer, Research Programs Review, Branch Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room

7W610, Rockville, MD 20892–9750, 240–276–6459, *biancoc@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Provocative Question #10.

Date: November 3, 2016.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W030, Rockville, MD 20850, (Telephone Conference Call).

Contact Person: Denise L. Stredrick, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W640, Rockville, MD 20892–9750, 240–276–5053, *stredrid@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: July 22, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–17810 Filed 7–27–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: National Center of Excellence for Infant and Early Childhood Mental Health Consultation—NEW

The Substance Abuse and Mental Health Services Administration's (SAMHSA), Center for Mental Health Services, in partnership with the Health Resources and Services Administration (HRSA) and the Administration for Children and Families (ACF), announces the establishment of the National Center of Excellence (CoE) for Infant and Early Childhood Mental Health Consultation (IECMHC), a new program to advance the implementation of high-quality infant and early childhood mental health consultation across the nation through the development of tools, resources, training, technical assistance, and collaborative public and private partnerships. Its primary goals will be to promote the healthy social and emotional development of infants and young children and to prevent mental, emotional and behavioral disorders within this age group. Major activities for the CoE include convening a national expert workgroup and to lead the workgroup in developing a state-of-the-art Toolkit of the latest research and best practices for IECMHC (*e.g.,* training, implementation, evaluation and financing) for early childhood settings, including early care and education and home visiting programs. The CoE will also create a dissemination and training plan for the Toolkit, and provide intensive training and technical assistance to states and tribes to help them build their capacity to implement, fund and evaluate IECMHC efforts successfully.

To monitor the reach, implementation and impact of the CoE's multiple efforts, learn which practices work for which populations, and gauge overall applicability and utility of the Toolkit to infant and early childhood mental health consultation, the CoE intends to employ a variety of standardized process and outcome measures that have been specifically designed to reduce participant burden. Measures will explore the related professional background and experience of IECMHC participants, degree of satisfaction with IECMHC trainings and technical assistance (TTA), usefulness of the TTA, areas for improvement, scope of IECMHC implementation across the State or Tribe, and IECMHC impact on childcare and pre-K expulsion rates.

Data-collection efforts will focus on two types of respondents: (1) Mental health consultants employed at maternal and child health, behavioral health, child care, Head Start, education and child welfare agencies, and (2) State or tribal representatives who have been selected to lead the implementation, expansion and sustainability of IECMHC in their state or tribal community.

The mental health consultants will be asked to provide background information on their prior experience in the IECMHC field, feedback immediately following the trainings, and follow-up feedback approximately two months after receiving training and/or technical assistance. Specific sample questions will include level of satisfaction with the training/technical assistance, perceptions of knowledge acquired, intentions to use training content, extent of implementation of content, and opinions regarding the training's cultural appropriateness for its audience.

State/tribal representatives will be asked to report on the reach and impact of the IECMHC program in the past year, level of satisfaction with IECMHC, suggested improvements for the program, and emerging state/tribal needs that the program could address. IECMHC mentors, whose primary role will be to work with the state/tribal representatives to implement the IECMHC Toolkit, will gather specific information from the representatives, including recommended IECMHC professional standards for mental health consultants, state- or tribal-level evaluations of IECMHC impact, and financing for the continuation of IECMHC. For programs also receiving funding from the Maternal Infant and Early Childhood Home Visiting (MIECHV) program, representatives will be asked to report on selected MIECHV outcome measures relating to maternal and newborn health; school readiness and achievement; and coordination and referrals for other community resources and supports.

SAMHSA will use this data to determine whether funded activities are progressing as expected, provide guidance to improve how work is being conducted, assess the impact of IECMHC on child-serving systems, and inform subsequent national, state, tribal and community policy and planning decisions.

ESTIMATE OF RESPONDENT BURDEN

[Note: Total burden is annualized over the 3-year clearance period]

Instrument	Number of respondents	Average number of responses per respondent per year	Total number of responses	Hours per response	Total annual burden hours
Service Pre-Assessment Form	150	6	900	.167	150.30
Training Feedback Form	112	6	672	.167	112.22
Training Follow-up Form	112	4	448	.167	74.82
Technical Assistance Follow-up Form	30	6	180	.167	30.06
IECMHC Cumulative Services Assessment Form	17	1	17	.333	5.66
IECMHC Annual and Quarterly Benchmark Data Collection Forms	17	4	68	1.5	102.00
Totals	438	27	2,285	....	475.06

Send comments to Summer King, SAMHSA Reports Clearance Officer, 5600 Fishers Lane, Room 15E57–B, Rockville, Maryland 20857, *OR* email a copy to *summer.king@samhsa.hhs.gov.* Written comments should be received by September 26, 2016.

Summer King,
Statistician.

[FR Doc. 2016–17867 Filed 7–27–16; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

U. S. Customs and Border Protection

Notice Announcing the Automated Commercial Environment (ACE) Protest Module as the Sole CBP-Authorized Method for Filing Electronic Protests

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: General notice.

SUMMARY: This document announces that the Automated Commercial Environment (ACE) Protest Module will be the sole method authorized by the Commissioner of U.S. Customs and Border Protection (CBP) for filing electronic protests. This document also announces that CBP will no longer accept protests filed through the Automated Broker Interface (ABI) to the Automated Commercial System (ACS). Upon the effective date of this notice, ACE will replace ACS as the electronic data interchange system authorized for protest filing.

DATES: Effective August 29, 2016, the ACE Protest Module will be the sole CBP-authorized method for filing electronic protests.

FOR FURTHER INFORMATION CONTACT: For technical questions related to the ACE Protest Module, or to request an ACE Protest Account in the ACE Portal, contact your assigned client representative. Interested parties without an assigned client representative should direct their questions to Steven Zaccaro at *steven.j.zaccaro@cbp.dhs.gov* with the subject heading "ACE Protest Module."

SUPPLEMENTARY INFORMATION:

Background

Statutory Authority

Section 514 of the Tariff Act of 1930, as amended (19 U.S.C. 1514), provides that certain decisions made by CBP can be protested within 180 days of the date of liquidation, *i.e.,* the date on which CBP's decision becomes final. Section 645 of Subtitle B of Title VI of the North American Free Trade Agreement Implementation Act (Pub. L. 103–182, 107 Stat. 2057, December 8, 1993), commonly known as the Customs Modernization Act, or Mod Act, amended section 514(c)(1) of the Tariff Act of 1930 (19 U.S.C. 1514(c)(1)) to permit the transmission of such protests to CBP electronically pursuant to an electronic data interchange system.

Current Regulations

The CBP regulations governing protests are found in part 174 of Title 19 of the Code of Federal Regulations (19 CFR part 174).

On January 14, 2011, CBP published a Final Rule in the **Federal Register** (76 FR 2573) making technical corrections to part 174 and related provisions in Title 19 of the Code of Federal Regulations. The rule amended section 174.12(b) to conform to section 514(c)(1) of the Tariff Act of 1930, allowing a protest to be transmitted electronically, using the electronic data interchange system authorized by CBP for that purpose.

Currently, CBP accepts electronic protests submitted through the Automated Broker Interface (ABI) to the Automated Commercial System (ACS), the electronic data interchange system currently authorized by CBP for this purpose.

Transition From ACS to ACE

In an effort to modernize the business processes essential to securing U.S. borders, facilitating the flow of legitimate shipments, and targeting illicit goods pursuant to the Mod Act and the Security and Accountability for Every (SAFE) Port Act of 2006 (Pub. L. 109–347, 120 Stat. 1884), CBP developed the Automated Commercial Environment (ACE) to eventually replace ACS. Over the last several years, CBP has tested ACE and provided significant public outreach to ensure that the trade community is fully aware of the transition from ACS to ACE. CBP is now transitioning electronic protest filing from ACS to ACE. Upon the effective date of this notice, ACE will replace ACS as the electronic data interchange system authorized for protest filing.

ACE Protest Module as the Sole CBP-Authorized Method for the Filing of Electronic Protests

This notice announces that the ACE Protest Module will be the sole CBP-authorized method for filing electronic protests. Filers who intend to submit a protest electronically must use the ACE Protest Module. The ACE Protest Module is an internet-based processing module which allows a filer to submit an electronic protest to ACE for processing by CBP. Protest filings will no longer be accepted in ACS. This transition has no effect on filers who intend to submit their protest in paper form, as specified in 19 CFR part 174.

Dated: July 22, 2016.

R. Gil Kerlikowske,

Commissioner, U.S. Customs and Border Protection.

[FR Doc. 2016–17915 Filed 7–27–16; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R5–ES–2015–N203]; [50120–1112–0000–F2]

Receipt of an Application for an Incidental Take Permit for Karner Blue Butterfly, From the Slack Chemical Company, and Availability of Proposed Habitat Conservation Plan

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability, receipt of application.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the availability of an application for an Incidental Take Permit (ITP) and a proposed Habitat Conservation Plan (HCP) from the Slack Chemical Company for public review and comment. We received the permit application from the Slack Chemical Company for incidental take of the endangered Karner blue butterfly resulting from the construction of a gravel access road, as well as from proposed mitigation activities over the next 10 years. Our preliminary determination is that the proposed HCP qualifies as low-effect in accordance with our Handbook for Habitat Conservation Planning and Incidental Taking Permitting Process. To make this determination, we used our Low-Effect HCP Screening Form/Environmental Action Statement (EAS), the preliminary version of which is also available for review.

We provide this notice to (1) seek public comments on the proposed HCP and application; (2) seek public comments on our preliminary determination that the HCP qualifies as low-effect and is therefore eligible for a categorical exclusion under the National Environmental Policy Act (NEPA); and (3) advise other Federal and State agencies, affected Tribes, and the public of our intent to issue an ITP.

DATES: To ensure consideration, we must receive your written comments by August 29, 2016.

ADDRESSES: *Reviewing documents:* You may obtain copies of the proposed HCP and preliminary EAS for review by any of the following methods:

Internet: New York Field Office Web site, at *http://www.fws.gov/northeast/nyfo/;*

In-person: Copies will be available for public review during regular business hours at the New York Field Office (see **FOR FURTHER INFORMATION CONTACT**);

U.S. mail: You may request copies by sending a letter to the New York Field Office (see **FOR FURTHER INFORMATION CONTACT**); or

Telephone: Those who do not have access to the Web site or cannot visit our office may request copies by telephone at 607–753–9334.

Submitting comments: You may submit written comments by any one of the following methods:

Email: FW5ES_NYFO@fws.gov. Please put Slack Chemical HCP in the subject line; or

U.S. mail: Noelle Rayman-Metcalf (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Noelle Rayman-Metcalf, by U.S. mail at U.S. Fish and Wildlife Service, New York Field Office, 3817 Luker Road, Cortland, NY 13045; or via phone at 607–753–9334.

SUPPLEMENTARY INFORMATION: We received an application from the Slack Chemical Company for an ITP for take of the federally listed endangered Karner blue butterfly (*Lycaeides melissa samuelis*) resulting from the construction of a gravel access road, as well as from proposed mitigation activities. To minimize and mitigate for the incidental take, the Slack Chemical Company will implement a conservation program as described in its proposed HCP. We prepared a preliminary EAS to comply with NEPA. The Service will evaluate whether the proposed action, issuance of an ITP to the Slack Chemical Company, is adequate to support a categorical exclusion. We are requesting comments on the proposed HCP and our preliminary determination that the plan qualifies as low-effect under NEPA.

Background

Section 9 of the Act (16 U.S.C. 1531 *et seq.*) and its implementing regulations prohibit the "take" of animal species listed as endangered or threatened. Take is defined under the Act as to "harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect listed animal species, or to attempt to engage in such conduct" (16 U.S.C. 1538). However, under section 10(a) of the Act, we may issue permits to authorize incidental take of listed species. "Incidental take" is defined by the Act as take that is incidental to, and not the purpose of, carrying out an otherwise lawful activity. Regulations governing incidental take permits for threatened and endangered species, respectively, are found in the Code of Federal Regulations (October 1, 2006, 50 CFR 17.22; October 1, 2001, 50 CFR 17.32).

Proposed Project

Slack Chemical Company is seeking a permit for the incidental take of the Karner blue butterfly for a term of 10 years. Incidental take of this species will occur in an approximate 0.10-acre area within a National Grid right-of-way (ROW). Slack Chemical Company proposes to construct a gravel access road through the ROW to access approximately 8 acres for construction of a parking lot for their trucking fleet and a building. The project is located in Grande Industrial Park, Saratoga Springs, Saratoga County, New York. An additional 4.81 acres of temporary impacts to enhance Karner blue butterfly habitat will occur due to periodic mowing.

Proposed covered activities include the new construction of a gravel access road, as well as periodic mowing of occupied habitat of two existing New York State Department of Environmental Conservation management areas, and one National Grid easement area, as well as the seeding of wild blue lupine and other nectar species within a 0.10 acre patch in National Grid's ROW. The HCP's proposed conservation strategy is designed to minimize and mitigate the impacts of covered activities on the covered species. The biological goal is to complement the existing conservation efforts in New York State for the butterfly.

The proposed action consists of the issuance of an ITP and implementation of the proposed HCP. One alternative to the proposed action was considered in the HCP: No action (*i.e.*, operation of the project without an ITP and without avoidance, minimization, or mitigation of Karner blue butterfly impacts). This alternative was deemed not practicable by Slack Chemical Company because the project would not have the important protections of the ITP and would not have the conservation benefits proposed by the Slack Chemical Company.

National Environmental Policy Act

We have made a preliminary determination that the Slack Chemical Company's proposed HCP, including proposed minimization and mitigation measures, will have a minor or negligible effect on the species covered in the plan, and that the plan qualifies as a "low-effect" HCP as described in the Service's HCP Handbook (61 FR 63854, December 2, 1996). Therefore, our proposed issuance of the requested incidental take permit qualifies as a categorical exclusion under the National Environmental Policy Act, as provided by Department of the Interior implementing regulations in part 46 of title 43 of the Code of Federal Regulations (43 CFR 46.205, 46.210, and 46.215).

As further explained in the preliminary EAS, included for public review, our preliminary determination that the plan qualifies as a low-effect HCP is based on the following three criteria:

(1) Implementation of the plan would result in minor or negligible effects on federally listed, proposed, and candidate species and their habitats;

(2) Implementation of the plan would result in minor or negligible effects on other environmental values or resources prior to implementation of the mitigation measures; and

(3) Impacts of the plan, considered together with the impacts of other past, present, and reasonably foreseeable similarly situated projects, would not result, over time, in cumulative effects to the environmental values or resources that would be considered significant.

Next Steps

We will evaluate the proposed HCP and comments we receive to determine whether the permit application meets the requirements of section 10(a) of the ESA (16 U.S.C. 1531 *et seq.*). We will also evaluate whether issuance of a section 10(a)(1)(B) permit would comply with section 7 of the ESA by conducting an intra-Service section 7 consultation. We will use the results of this consultation, in combination with the above findings, in our final analysis to determine whether or not to issue a permit. If the requirements are met, we will issue the permit to the applicant.

Public Comments

We invite the public to comment on the proposed HCP and preliminary EAS during a 30-day public comment period (see **DATES**). You may submit written comments by one of the methods in the **ADDRESSES** section.

All comments received, including names and addresses, will become part of the administrative record and will be available to the public. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—will be publicly available. If you submit a hard copy comment that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so.

Authority

We provide this notice pursuant to section 10(c) of the ESA (16 U.S.C. 1531 *et seq.*) and NEPA regulations (40 CFR 1506.6).

Dated: July 21, 2016.

Cindy Schulz,

Acting Assistant Regional Director—Ecological Services, Northeast Region.

[FR Doc. 2016–17866 Filed 7–27–16; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX16GC009PLSS00]

National Cooperative Geologic Mapping Program (NCGMP) and National Geological and Geophysical Data Preservation Program (NGGDPP) Advisory Committee

AGENCY: U.S. Geological Survey, Interior.

ACTION: Notice of annual meeting: Audio conference.

SUMMARY: Pursuant to Public Law 106–148, the NCGMP and NGGDPP Advisory Committee will hold an audio conference call on Thursday, September 22, 2016, from 9 a.m.–5 p.m. Eastern Standard Time. The Advisory Committee, comprising representatives from Federal agencies, State agencies, academic institutions, and private companies, shall advise the Director of the U.S. Geological Survey on planning and implementation of the geologic mapping and data preservation programs.

The Committee will hear updates on progress of the NCGMP toward fulfilling the purposes of the National Geological Mapping Act of 1992, as well as updates on the NGGDPP toward fulfilling the purposes of the Energy Policy Act of 2005.

Retraction: Please note that this meeting was originally scheduled for August 8, 2016 and a notice was published in the **Federal Register**, dated June 13, 2016. The original advertised date of this meeting is no longer accurate and the meeting has been postponed to September 22, 2016.

DATES: September 22, 2016, from 9 a.m.–5 p.m. Eastern Standard Time.

FOR FURTHER INFORMATION CONTACT: For the phone number and access code, please contact Michael Marketti, U.S. Geological Survey, Mail Stop 908, National Center, Reston, Virginia 20192, (703) 648–6976.

SUPPLEMENTARY INFORMATION: Meetings of the National Cooperative Geologic Mapping Program and National Geological and Geophysical Data Preservation Program Advisory Committee are open to the public.

Dated: July 25, 2016.

Michael J. Marketti,

Program Analyst, NCGMP.

[FR Doc. 2016–17882 Filed 7–27–16; 8:45 am]

BILLING CODE 4311–AM–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMTC02900.L16100000.DF0000]

Notice of Public Meeting, Dakotas Resource Advisory Council Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Public Meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act (FLPMA) and the Federal Advisory Committee Act of 1972 (FACA), the U.S. Department of the Interior, Bureau of Land Management (BLM) Dakotas Resource Advisory Council (RAC) will meet as indicated below.

DATES: The Dakotas Resource Advisory Council meeting will be held on August 25, 2016. When determined, the meeting location and times will be announced in a news release.

FOR FURTHER INFORMATION CONTACT: Mark Jacobsen, Public Affairs Specialist, BLM Eastern Montana/Dakotas District, 111 Garryowen Road, Miles City, Montana, 59301; (406) 233–2831; *mjacobse@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–677–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The 15-member council advises the Secretary of the Interior through the BLM on a variety of planning and management issues associated with public land management in eastern Montana. At this meeting, topics will include: An Eastern Montana/Dakotas District report, North Dakota and South Dakota Field Office manager reports, individual RAC member reports, coal industry and BLM coal program discussion and other issues the council may raise. All meetings are open to the public and the public may present written comments to the council. Each formal RAC meeting will have time allocated for hearing public comments. Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited. Individuals who plan to attend and need special assistance, such as sign language interpretation, tour transportation or other reasonable accommodations should contact the BLM as provided above.

Authority: 43 CFR 1784.4–2.

Diane M. Friez,

Eastern Montana/Dakotas District Manager.

[FR Doc. 2016–17869 Filed 7–27–16; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNM950000 L13400000.BX0000 16XL1109AF]

Notice of Filing of Plats of Survey, New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Filing of Plats of Survey.

SUMMARY: The plats of survey described below are scheduled to be officially filed in the New Mexico State Office, Bureau of Land Management, Santa Fe, New Mexico, thirty (30) calendar days from the date of this publication.

FOR FURTHER INFORMATION CONTACT: These plats will be available for inspection in the New Mexico State Office, Bureau of Land Management, 301 Dinosaur Trail, Santa Fe, New Mexico. Copies may be obtained from this office upon payment. Contact Carlos Martinez at 505–954–2096, or by email at *cjjmarti@blm.gov,* for assistance. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours.

SUPPLEMENTARY INFORMATION:

New Mexico Principal Meridian, New Mexico (NM)

The Supplemental plat, representing the dependent resurvey in Township 16 South, Range 13 West, of the New Mexico Principal Meridian, accepted January 14, 2016 for Group, 1173, NM.

The Supplemental plat, representing the dependent resurvey in Township 16 South, Range 13 West, of the New Mexico Principal Meridian, accepted January 14, 2016 for Group, 1173, NM.

The Supplemental plat, representing the dependent resurvey in Township 16 South, Range 14 West, of the New Mexico Principal Meridian, accepted January 14, 2016 for Group, 1173, NM.

The plat, representing the dependent resurvey in Township 30 North, Range 20 West, of the New Mexico Principal Meridian, accepted February 29, 2016 for Group, 1162, NM.

The plat, representing the dependent resurvey in Township 15 North, Range 6 East, of the New Mexico Principal Meridian, accepted March 1, 2016 for Group, 1167, NM.

The plat, in 5 pages, representing the dependent resurvey for the La Majada Grant, of the New Mexico Principal Meridian, accepted March 1, 2016 for Group, 1167, NM.

The plat, in 3 pages, representing the dependent resurvey in Township 19 North, Range 18 West, of the New Mexico Principal Meridian, accepted May 23, 2016 for Group, 1160, NM.

The Indian Meridian, Oklahoma (OK)

The plat, representing the dependent resurvey and survey in Township 3 South, Range 5 East, of the Indian Meridian, accepted February 24, 2016, for Group 227 OK.

These plats are scheduled for official filing 30 days from the notice of publication in the **Federal Register**, as provided for in the BLM Manual Section 2097—Opening Orders. Notice from this office will be provided as to the date of said publication. If a protest against a survey, in accordance with 43 CFR 4.450–2, of the above plats is received prior to the date of official filing, the filing will be stayed pending consideration of the protest.

A plat will not be officially filed until the day after all protests have been dismissed and become final or appeals from the dismissal affirmed.

A person or party who wishes to protest against any of these surveys must file a written protest with the Bureau of Land Management New Mexico State Director stating that they wish to protest.

A statement of reasons for a protest may be filed with the Notice of Protest to the State Director or the statement of reasons must be filed with the State Director within thirty (30) days after the protest is filed.

Charles I. Doman,

Branch Chief, Cadastral Survey.

[FR Doc. 2016–17868 Filed 7–27–16; 8:45 am]

BILLING CODE 4310–FB–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–298 (Fourth Review)]

Porcelain-on-Steel Cooking Ware From China; Determination

On the basis of the record[1] developed in the subject five-year review, the United States International Trade Commission ("Commission") determines, pursuant to the Tariff Act of 1930 ("the Act"), that revocation of the antidumping duty order on porcelain-on-steel cooking ware from China would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[2]

Background

The Commission, pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)), instituted this review on February 1, 2016 (81 FR 5133) and determined on May 6, 2016 that it would conduct an expedited review (81 FR 32345, May 23, 2016).

The Commission made this determination pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determination in this review on July 22, 2016. The views of the Commission are contained in USITC Publication 4625 (July 2016), entitled *Porcelain-on-Steel Cooking Ware from China: Investigation No. 731–TA–298 (Fourth Review).*

By order of the Commission.

Issued: July 22, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–17831 Filed 7–27–16; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

182nd Meeting of the Advisory Council on Employee Welfare and Pension Benefit Plans; Notice of Meeting

Pursuant to the authority contained in Section 512 of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1142, the 182nd meeting of the Advisory Council on Employee Welfare and Pension Benefit Plans (also known as the ERISA Advisory Council) will be held on August 23–25, 2016.

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[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] Commissioner Meredith A. Broadbent not participating.

The three-day meeting will take place at the U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210 in C5521 Room 4. The meeting will run from 9:00 a.m. to approximately 5:30 p.m. on August 23–24, with a one hour break for lunch each day, and from 9:00 a.m. to 12:00 p.m. on August 25. The purpose of the open meeting is for Advisory Council members to hear testimony from invited witnesses and to receive an update from the Employee Benefits Security Administration (EBSA). The EBSA update is scheduled for the morning of August 25, subject to change.

The Advisory Council will study the following topics: (1) Participant Plan Transfers and Account Consolidation for the Advancement of Lifetime Plan Participation, on August 23 and (2) Cybersecurity Considerations for Benefit Plans, on August 24. The schedule is subject to change. Witnesses may testify on one or both issues on either August 23 or 24. Descriptions of these topics are available on the Advisory Council page of the EBSA Web site, at *www.dol.gov/ebsa/aboutebsa/erisa_advisory_council.html.*

Organizations or members of the public wishing to submit a written statement may do so by submitting 35 copies on or before August 16, 2016 to Larry Good, Executive Secretary, ERISA Advisory Council, U.S. Department of Labor, Suite N–5623, 200 Constitution Avenue NW., Washington, DC 20210. Statements also may be submitted as email attachments in word processing or pdf format transmitted to *good.larry@dol.gov.* It is requested that statements not be included in the body of the email. Statements deemed relevant by the Advisory Council and received on or before August 16 will be included in the record of the meeting and made available through the EBSA Public Disclosure Room, along with witness statements. Do not include any personally identifiable information (such as address or other contact information) or confidential business information that you do not want publicly disclosed.

Individuals or representatives of organizations wishing to address the Advisory Council should forward their requests to the Executive Secretary or telephone (202) 693–8668. Oral presentations will be limited to 10 minutes, time permitting, but an extended statement may be submitted for the record. Individuals with disabilities who need special accommodations should contact the Executive Secretary by August 16.

Signed at Washington, DC, this 20th day of July, 2016.

Judith Mares,

Deputy Assistant Secretary, Employee Benefits Security Administration.

[FR Doc. 2016–17723 Filed 7–27–16; 8:45 am]

BILLING CODE 4510–29–P

OFFICE OF MANAGEMENT AND BUDGET

Revision of OMB Circular No. A–130, "Managing Information as a Strategic Resource"

AGENCY: Office of Management and Budget, Executive Office of the President.

ACTION: Notice of availability.

SUMMARY: The Office of Management and Budget (OMB) has revised Circular A–130, "Managing Information as a Strategic Resource," to reflect changes in law and advances in technology. The revisions also ensure consistency with executive orders, presidential directives, recent OMB policy, and National Institute of Standards and Technology standards and guidelines.

The Circular establishes general policy for information governance, acquisitions, records management, open data, workforce, security, and privacy. It also emphasizes the role of both privacy and security in the Federal information life cycle. Importantly, it represents a shift from viewing security and privacy requirements as compliance exercises to understanding security and privacy as crucial elements of a comprehensive, strategic, and continuous risk-based program at Federal agencies.

When implemented by agencies, these revisions to the Circular will promote innovation, enable appropriate information sharing, and foster the wide-scale and rapid adoption of new technologies while strengthening protections for security and privacy.

DATES: Effective Upon Publication As of July 28, 2016 OMB is making revised Circular A–130 available to the public.

Circular is available at *https://www.whitehouse.gov/omb/circulars_default/.*

Rescission: This Circular rescinds OMB Memoranda M–10–28, "Clarifying Cybersecurity Responsibilities and Activities of the Executive Office of the President and the Department of Homeland Security (DHS)."

FOR FURTHER INFORMATION CONTACT: Carol Bales, Office of Management and Budget, Office of the Federal Chief Information Officer, at *A130@omb.eop.gov.*

Shaun Donovan,

Director, Office of Management and Budget.

[FR Doc. 2016–17872 Filed 7–27–16; 8:45 am]

BILLING CODE P

NATIONAL SCIENCE FOUNDATION

Notice of Intent To Seek Approval To Extend a Current Information Collection

AGENCY: National Science Foundation.

ACTION: Notice and request for comments.

SUMMARY: The National Science Foundation (NSF) is announcing plans to request renewal of the National Survey of College Graduates (OMB Control Number 3145–0141). In accordance with the requirement of 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, Pub. L. 104–13, we are providing opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting that OMB approve clearance of this collection for three years.

Comments: Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the NSF, including whether the information will have practical utility; (b) the accuracy of the NSF's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected, including through the use of automated collection techniques or other forms of information technology; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology.

DATES: Written comments on this notice must be received by September 26, 2016, to be assured of consideration. Comments received after that date will be considered to the extent practicable.

For Additional Information or Comments: Contact Ms. Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 4201 Wilson Boulevard, Suite 1265, Arlington, Virginia 22230; telephone (703) 292–7556; or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–

800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays).

SUPPLEMENTARY INFORMATION:

Title of Collection: 2017 National Survey of College Graduates.

OMB Approval Number: 3145–0141.

Expiration Date of Approval: May 31, 2018.

Type of Request: Intent to seek approval to renew an information collection for three years.

Abstract: The National Survey of College Graduates (NSCG) has been conducted biennially since the 1970s. The 2017 NSCG sample will be selected from the 2015 American Community Survey (ACS) and the 2015 NSCG. By selecting sample from these two sources, the 2017 NSCG will provide coverage of the college graduate population residing in the United States. The purpose of this longitudinal survey is to collect data that will be used to provide national estimates on the science and engineering workforce and changes in their employment, education, and demographic characteristics.

The National Science Foundation Act of 1950, as subsequently amended, includes a statutory charge to ". . . provide a central clearinghouse for the collection, interpretation, and analysis of data on scientific and engineering resources, and to provide a source of information for policy formulation by other agencies of the Federal Government." The NSCG is designed to comply with these mandates by providing information on the supply and utilization of the nation's scientists and engineers.

The U.S. Census Bureau, as in the past, will conduct the NSCG for NSF. The survey data collection will begin in February 2017 using web and mail questionnaires. Nonrespondents to the web or mail questionnaire will be followed up by computer-assisted telephone interviewing. The individual's response to the survey is voluntary. The survey will be conducted in conformance with Census Bureau statistical quality standards and, as such, the NSCG data will be afforded protection under the applicable Census Bureau confidentiality statues.

Use of the Information: The NSF uses the information from the NSCG to prepare congressionally mandated reports such as *Women, Minorities and Persons with Disabilities in Science and Engineering* and *Science and Engineering Indicators.* A public release file of collected data, designed to protect respondent confidentiality, will be made available to researchers on the Internet.

Expected Respondents: A statistical sample of approximately 118,000 individuals will be contacted in 2017. NSF expects the response rate to be 70 to 80 percent.

Estimate of Burden: The amount of time to complete the questionnaire may vary depending on an individual's circumstances; however, on average it will take approximately 30 minutes to complete the survey. NSF estimates that the total annual burden will be no more than 47,200 hours (= 118,000 respondents × 80% response × 30 minutes) during the 2017 survey cycle.

Dated: July 25, 2016.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2016–17874 Filed 7–27–16; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 52–027 and 52–028; NRC–2008–0441]

Virgil C. Summer Nuclear Station, Units 2 and 3; South Carolina Electric & Gas Company; Main Control Room Emergency Habitability System Design Changes

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption and combined license amendment; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is granting an exemption to allow a departure from the certification information of Tier 1 of the generic design control document (DCD) and is issuing License Amendment No. 49 to Combined Licenses (COLs), NPF–93 and NPF–94. The COLs were issued to South Carolina Electric & Gas (SCE&G) (the licensee); for construction and operation of the Virgil C. Summer Nuclear Station (VCSNS) Units 2 and 3, located in Fairfield County, South Carolina. The granting of the exemption allows the changes to Tier 1 information asked for in the amendment. Because the acceptability of the exemption was determined in part by the acceptability of the amendment, the exemption and amendment are being issued concurrently.

DATES: The exemption and combined license amendment referenced in this document are available on July 28, 2016.

ADDRESSES: Please refer to Docket ID NRC–2008–0441 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2008–0441. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "ADAMS Public Documents" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced. The request for the amendment and exemption was submitted by letter dated June 30, 2015 (ADAMS Accession No. ML15181A470)
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Paul Kallan, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2809; email: *Paul.Kallan@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is granting an exemption from paragraph B of section III, "Scope and Contents," of Appendix D, "Design Certification Rule for the AP1000," to part 52 of title 10 of the *Code of Federal Regulations* (10 CFR) and issuing License Amendment No. 49 to COLs, NPF–93 and NPF–94, to the licensee. The exemption is required by paragraph A.4 of Section VIII, "Processes for Changes and Departures," Appendix D, to 10 CFR part 52 to allow the licensee to depart from Tier 1 information. With the requested amendment, the licensee sought proposed changes that would revise ASME safety classification and transition location, equipment orientation and removal, and identification of the number of emergency air storage tanks. The proposed changes to the Main Control Room Emergency Habitability System (VES) revises Tier 1 and corresponding information in COL Appendix C, Figure 2.2.5–1. It also revises Tier 2 information in the Updated Final Safety Analysis Report.

Part of the justification for granting the exemption was provided by the review of the amendment. Because the exemption is necessary in order to issue the requested license amendment, the NRC granted the exemption and issued the amendment concurrently, rather than in sequence. This included issuing a combined safety evaluation containing the NRC staff's review of both the exemption request and the license amendment. The exemption met all applicable regulatory criteria set forth in 10 CFR 50.12, 10 CFR 52.7, and Section VIII.A.4 of Appendix D to 10 CFR part 52. The license amendment was found to be acceptable as well. The combined safety evaluation is available in ADAMS under Accession No. ML16095A202.

Identical exemption documents (except for referenced unit numbers and license numbers) were issued to the licensee for VCSNS Units 2 and 3 (COLs NPF–93 and NPF–94). The exemption documents for VCSNS Units 2 and 3 can be found in ADAMS under Accession Nos. ML16095A141 and ML16095A144, respectively. The exemption is reproduced (with the exception of abbreviated titles and additional citations) in Section II of this document. The amendment documents for COLs NPF–93 and NPF–94 are available in ADAMS under Accession Nos. ML16095A132 and ML16095A137, respectively. A summary of the amendment documents is provided in Section III of this document.

II. Exemption

Following is the exemption document issued to VCSNS Units 2 and Unit 3. It makes reference to the combined safety evaluation that provides the reasoning for the findings made by the NRC (and listed under Item 1) in order to grant the exemption:

1. In a letter dated June 30, 2015, the licensee requested from the Commission an exemption from the provisions of 10 CFR part 52, appendix D, section III.B, as part of license amendment request 15–03, "Main Control Room Emergency Habitability System (VES) Design Changes (LAR 15–03)."

For the reasons set forth in Section 3.1, "Evaluation of Exemption," of the NRC staff's Safety Evaluation, which can be found in ADAMS under Accession No. ML16095A202, the Commission finds that:

A. The exemption is authorized by law;

B. the exemption presents no undue risk to public health and safety;

C. the exemption is consistent with the common defense and security;

D. special circumstances are present in that the application of the rule in this circumstance is not necessary to serve the underlying purpose of the rule;

E. the special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the exemption; and

F. the exemption will not result in a significant decrease in the level of safety otherwise provided by the design.

2. Accordingly, the licensee is granted an exemption from the certified DCD Tier 1, as described in the licensee's request dated June 30, 2015. This exemption is related to, and necessary for the granting of License Amendment No. 49, which is being issued concurrently with this exemption.

3. As explained in Section 5.0, "Environmental Consideration," of the NRC staff's Safety Evaluation (ADAMS Accession No. ML16095A202), this exemption meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(9). Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment needs to be prepared in connection with the issuance of the exemption.

4. This exemption is effective as of the date of its issuance.

III. License Amendment Request

By letter dated June 30, 2015, the licensee requested that the NRC amend the COLs for VCSNS, Units 2 and 3, COLs NPF–93 and NPF–94. The proposed amendment is described in Section I of this **Federal Register** Notice.

The Commission has determined for these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating license or combined license, as applicable, proposed no significant hazards consideration determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** on October 15, 2015 (80 FR 61476). No comments were received during the 30-day comment period.

The Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments.

IV. Conclusion

Using the reasons set forth in the combined safety evaluation, the staff granted the exemption and issued the amendment that the licensee requested on June 30, 2015. The exemption and amendment were issued on June 2, 2016, as part of a combined package to the licensee (ADAMS Accession No. ML16095A115).

Dated at Rockville, Maryland, this 18th day of July 2016.

For the Nuclear Regulatory Commission.

Jennifer Dixon-Herrity,

Acting Chief, Licensing Branch 4, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. 2016–17918 Filed 7–27–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[IA–16–026; NRC–2016–0150]

In the Matter of Kyle Lynn Dickerson

AGENCY: Nuclear Regulatory Commission.

ACTION: Confirmatory order; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) issued a confirmatory order to Kyle Lynn Dickerson confirming agreements reached in an Alternative Dispute Resolution mediation session held on June 3, 2016. As part of the agreement, Mr. Dickerson has completed and will complete future agreed upon actions within 18 months of the issuance date of the confirmatory order.

DATES: The confirmatory order was issued on July 11, 2016.

ADDRESSES: Please refer to Docket ID NRC–2016–0150 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0150. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For questions about the Order, contact the individual listed in the **FOR FURTHER**

INFORMATION CONTACT section of this document.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "*ADAMS Public Documents*" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: John Kramer, Region IV, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 817–200–1121; email: *John.Kramer@nrc.gov.*

SUPPLEMENTARY INFORMATION: The text of the Order is attached.

Dated at Arlington, Texas, this 11th day of July 2016.

For the Nuclear Regulatory Commission.

Kriss M. Kennedy,

Regional Administrator.

UNITED STATES OF AMERICA NUCLEAR REGULATORY COMMISSION

In the Matter of Kyle Lynn Dickerson IA–16–026

Confirmatory Order

I.

Mr. Kyle Lynn Dickerson is a radiographer employed by Acuren USA in Kenai, Alaska. Acuren USA is the holder of license 50–32443–01 issued by the U.S. Nuclear Regulatory Commission (NRC or Commission) pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR part 30) on December 17, 2012.

This Confirmatory Order is the result of an agreement reached between Mr. Dickerson and the NRC during an alternative dispute resolution (ADR) mediation session conducted on June 3, 2016.

II.

On August 21, 2014, the NRC's Office of Investigations, Region IV Field Office, initiated an investigation to determine if radiographers assigned to the Acuren USA facility in Kenai, Alaska, willfully conducted radiographic operations without maintaining direct visual surveillance of the operation and without the proper postings. The investigation was completed on August 17, 2015, and was documented in NRC Investigation Report 4–2014–043.

Based on the evidence developed during the investigation, the NRC has concluded that a violation of 10 CFR 30.10(a)(1) occurred. Specifically, on April 10, 2014, Mr. Dickerson caused Acuren USA to be in violation of 10 CFR 34.51 and 10 CFR 34.53 by performing industrial radiographic operations without conspicuously posting the area with radiation area and high radiation area signs, and without maintaining continuous direct visual surveillance of the operation to protect against unauthorized entry into a high radiation area.

In a letter dated March 24, 2016 (ML16085A082), the NRC notified Mr. Dickerson of the results of the investigation, informed Mr. Dickerson that escalated enforcement action was being considered for an apparent violation, and provided Mr. Dickerson the opportunity to attend a predecisional enforcement conference or to participate in an ADR mediation session in an effort to resolve the concern. In response to the NRC's offer, Mr. Dickerson requested the use of the NRC's ADR process to resolve differences Mr. Dickerson had with the NRC. On June 3, 2016, the NRC and Mr. Dickerson met in an ADR session mediated by a professional mediator, arranged through Cornell University's Institute on Conflict Resolution. Alternative dispute resolution is a process in which a neutral mediator, with no decision-making authority, assists the parties in reaching an agreement on resolving any differences regarding the dispute. This Confirmatory Order is issued pursuant to the agreement reached during the ADR process.

III.

During the ADR session, Mr. Dickerson and the NRC reached a preliminary settlement agreement. The elements of the agreement recognized corrective actions that Mr. Dickerson already completed as described below and included future agreed upon actions as follows:

Corrective actions taken by Mr. Dickerson included:

A. Repeated annual refresher training, which included the following topics:

1. Changes to Acuren USA Operating and Emergency Manual.
2. Changes to Federal and State regulations.
3. Department of Transportation requirements and regulation changes.
4. Security Awareness and Emergency Planning.
5. Increased controls and 10 CFR part 37.
6. Violation and incident review.
7. Notification procedures.
8. Radiation surveys and documentation.
9. Equipment maintenance and documentation.
10. As Low As Reasonably Achievable (ALARA) commitment.

B. Successfully completed annual refresher training test for items described in Section A.

C. Completed training and review of the following regulatory documents:

1. 10 CFR parts 19, 20, 21, 30, 34, 37, and 71.
2. New NRC license issued December 17, 2012.
3. ROEM–2011, Revision 1 (Radiographic Operation Emergency Manual).
4. NRC Form 3 (Notice to Employees).
5. Alaska Department of Health and Social Services (DHSS), Radiation Protection.
6. Blank daily radiation reports.
7. Blank Trustworthiness and Reliability (T&R) escort log.
8. Blank exposure device utilization sign out sheet.
9. Shipper's declaration of dangerous goods.

D. Completed Radiographic Personnel Training, which included an examination and follow-up practical demonstrations of the following:

1. Use of an exposure device.
2. Use of personnel monitoring equipment.
3. Use of radiographic survey meters.
4. Performance of daily visual inspections.
5. Demonstration of leak test procedures.
6. Instructions of field audit examinations.

E. Successfully completed training and examination of:

1. "Golden Rules" of radiography.
2. "Buddy Check" systems.
3. Barrier controls.

F. Completed U.S. Department of Transportation, Hazmat, Emergency Planning, and Security Awareness Training.

G. Subjected to and passed additional Acuren USA field audits.

The elements of the agreement, as signed by both parties, consist of the following:

A. The NRC and Mr. Dickerson agreed that on April 10, 2014, Mr. Dickerson caused Acuren USA to be in violation of 10 CFR 34.51 and 10 CFR 34.53 by performing industrial radiographic operations without conspicuously posting the area with radiation and high radiation area signs and without maintaining continuous direct visual surveillance of the operation to protect against unauthorized entry into a high radiation area. However, the NRC and Mr. Dickerson disagree on the deliberate characterization of the violation. More specifically:

1. It is the NRC's view that the preponderance of the evidence supports the proposition that Mr. Dickerson deliberately performed industrial radiographic operations without conspicuously posting the area with radiation and high radiation area signs and without maintaining continuous direct visual surveillance of the operation to protect against unauthorized entry into a high radiation area.

2. However, Mr. Dickerson disagrees with the deliberate characterization of the violation.

B. Within 12 months of the issuance date of the Confirmatory Order, if supported by Mr. Dickerson's employer (currently Acuren USA), Mr. Dickerson will provide training to Acuren USA radiographers and radiographer's assistants.

1. Within 30 days before providing the training, Mr. Dickerson will submit the training agenda, materials, or content to the Director, Division of Nuclear Materials Safety (DNMS), Region IV.

2. The training (*e.g.,* peer-to-peer, teleconference, etc.) will convey personal lessons learned from the associated issue.

C. Within 18 months of the issuance date of the Confirmatory Order, Mr. Dickerson will meet with and observe (*i.e.,* "shadow") a radiation safety officer as the radiation safety officer performs observations of the performance of radiography crews as described in Section 34.43(e)(1) of 10 CFR part 34.

1. Mr. Dickerson will perform the field observations of at least four radiographic operations.

2. The observations will be conducted, to the extent possible, without the crew's knowledge.

3. The observations will be conducted at temporary job sites (*i.e.,* "in the field").

4. Mr. Dickerson will notify the Director, DNMS, Region IV, prior to the observations. This notification will be made by telephone at 817–200–1106 or email.

5. Within 1 month of the completion of each observation, Mr. Dickerson will provide written documentation to the NRC of the date that the observation occurred and the details of the observation (compliances and noncompliances observed, etc.). The information will be sent to the Director, DNMS, 1600 East Lamar Blvd., Arlington, Texas 76011–4511.

D. Within 18 months of the issuance date of the Confirmatory Order, Mr. Dickerson will submit an article to an industry publication or to a certifying entity (as defined in 10 CFR 34.3) for publication.

1. The article will convey personal lessons learned from the associated issue and may be co-written with the other radiographer involved with this case.

2. Mr. Dickerson will provide the article to the Director, DNMS, Region IV, 30 days prior to the submission of the article.

3. Mr. Dickerson will provide to the Director, DNMS, Region IV, demonstration of at least two attempts to publish the article, if publication of the article was not possible.

E. Administrative items.

1. The NRC and Mr. Dickerson agree that the above elements will be incorporated into a Confirmatory Order.

2. The NRC will consider the order an escalated enforcement action with respect to any future enforcement actions.

3. In consideration of the commitments delineated above, the NRC will refrain from issuing a Notice of Violation to Mr. Dickerson for the violation discussed in NRC Investigation Report 4–2014–043 and NRC Inspection Report 030–38596/2014–001 dated March 24, 2016 (IA–16–026).

On July 8, 2016, Mr. Dickerson consented to issuing this Confirmatory Order with the commitments, as described in Section V below. Mr. Dickerson further agreed that this Confirmatory Order will be effective upon issuance, the agreement memorialized in this Confirmatory Order settles the matter between the parties, and that Mr. Dickerson has waived his right to a hearing.

IV.

I find that Mr. Dickerson's commitments as set forth in Section V are acceptable and necessary, and conclude that with these commitments the public health and safety are reasonably assured. In view of the foregoing, I have determined that public health and safety require that Mr. Dickerson's commitments be confirmed by this Confirmatory Order. Based on the above and Mr. Dickerson's consent, this Confirmatory Order is effective upon issuance.

V.

Accordingly, pursuant to Sections 81, 161b, 161i, 161o, 182, and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR part 30, IT IS HEREBY ORDERED, THAT:

A. Within 12 months of the issuance date of the Confirmatory Order, if supported by Mr. Dickerson's employer (currently Acuren USA), Mr. Dickerson will provide training to Acuren USA radiographers and radiographer's assistants.

1. Within 30 days before providing the training, Mr. Dickerson will submit the training agenda, materials, or content to the Director, DNMS, Region IV.

2. The training (*e.g.,* peer-to-peer, teleconference, etc.) will convey personal lessons learned from the associated issue.

B. Within 18 months of the issuance date of the Confirmatory Order, Mr. Dickerson will meet with and observe (*i.e.,* "shadow") a radiation safety officer as the radiation safety officer performs observations of the performance of radiography crews as described in Section 34.43(e)(1) of 10 CFR part 34.

1. Mr. Dickerson will perform the field observations of at least four radiographic operations.

2. The observations will be conducted, to the extent possible, without the crew's knowledge.

3. The observations will be conducted at temporary job sites (*i.e.,* "in the field").

4. Mr. Dickerson will notify the Director, DNMS, Region IV, prior to the observations. This notification will be made by telephone at 817–200–1106 or email.

5. Within 1 month of the completion of each observation, Mr. Dickerson will provide written documentation to the NRC of the date that the observation occurred and the details of the observation (compliances and noncompliances observed, etc.). The information will be sent to the Director, Division of Nuclear Materials Safety, 1600 East Lamar Blvd., Arlington, Texas 76011–4511.

C. Within 18 months of the issuance date of the Confirmatory Order, Mr. Dickerson will submit an article to an industry publication or to a certifying entity (as defined in 10 CFR 34.3) for publication.

1. The article will convey personal lessons learned from the associated issue and may be co-written with the

other radiographer involved with this case.

2. Mr. Dickerson will provide the article to the Director, DNMS, Region IV, 30 days prior to the submission of the article.

3. Mr. Dickerson will provide to the Director, DNMS, Region IV, demonstration of at least two attempts to publish the article, if publication of the article was not possible within the 18 month period.

The Regional Administrator, Region IV, may, in writing, relax or rescind any of the above conditions upon demonstration by Mr. Dickerson of good cause.

VI.

In accordance with 10 CFR 2.202 and 10 CFR 2.309, any person adversely affected by this Confirmatory Order, other than Mr. Dickerson, may request a hearing within 30 days of the issuance date of this Confirmatory Order. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be directed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and include a statement of good cause for the extension.

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC E-Filing rule (72 FR 49139, August 28, 2007, as amended at 77 FR 46562, August 3, 2012), which is codified in pertinent part at 10 CFR part 2, subpart C. The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten (10) days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at (301) 415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/getting-started.html.* System requirements for accessing the E-Submittal server are detailed in NRC's "Guidance for Electronic Submission," which is available on the agency's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Electronic Filing Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System (EIE), users will be required to install a Web browser plug-in from the NRC Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the agency's adjudicatory E-Filing system may seek assistance by contacting the NRC Electronic Filing Help Desk through the "Contact Us" link located on the NRC's Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email at *MSHD.Resource@nrc.gov,* or by a toll-free call to (866) 672–7640. The NRC Electronic Filing Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket, which is available to the public at *http://ehd1.nrc.gov/ehd/,* unless excluded pursuant to an order of the Commission or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

If a person other than Mr. Dickerson requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Confirmatory Order and shall address the criteria set forth in 10 CFR 2.309(d) and (f).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Confirmatory Order should be sustained.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section V above shall be final 30 days from the date of issuance without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section V shall be final when the extension expires if a hearing request has not been received.

For the Nuclear Regulatory Commission.

Dated this 11th day of July 2016.

Kriss M. Kennedy,

Regional Administrator, Region IV.

[FR Doc. 2016–17920 Filed 7–27–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[IA–16–025; NRC–2016–0149]

In the Matter of Troy A. Morehead

AGENCY: Nuclear Regulatory Commission.

ACTION: Confirmatory order; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) issued a confirmatory order to Troy A. Morehead confirming agreements reached in an Alternative Dispute Resolution mediation session held on June 3, 2016. As part of the agreement, Mr. Morehead has completed and will complete future agreed upon actions within 18 months of the issuance date of the confirmatory order.

DATES: The confirmatory order was issued on July 11, 2016.

ADDRESSES: Please refer to Docket ID NRC–2016–0149 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0149. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For questions about the Order, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "*ADAMS Public Documents*" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: John Kramer, Region IV, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 817–200–1121; email: *John.Kramer@nrc.gov.*

SUPPLEMENTARY INFORMATION: The text of the Order is attached.

Dated at Arlington, Texas, this 11th day of July 2016.

For the Nuclear Regulatory Commission.

Kriss M. Kennedy,

Regional Administrator.

United States of America

Nuclear Regulatory Commission

In the Matter of Troy Allen Morehead IA–16–025 Confirmatory Order

I.

Mr. Troy Allen Morehead is a radiographer employed by Acuren USA in Kenai, Alaska. Acuren USA is the holder of license 50–32443–01 issued by the U.S. Nuclear Regulatory Commission (NRC or Commission) pursuant to title 10 of the *Code of Federal Regulations* (10 CFR) part 30 on December 17, 2012.

This Confirmatory Order is the result of an agreement reached between Mr. Morehead and the NRC during an alternative dispute resolution (ADR) mediation session conducted on June 3, 2016.

II.

On August 21, 2014, the NRC's Office of Investigations, Region IV Field Office, initiated an investigation to determine if radiographers assigned to the Acuren USA facility in Kenai, Alaska, willfully conducted radiographic operations without maintaining direct visual surveillance of the operation and without the proper postings. The investigation was completed on August 17, 2015, and was documented in NRC Investigation Report 4–2014–043.

Based on the evidence developed during the investigation, the NRC has concluded that a violation of 10 CFR 30.10(a)(1) occurred. Specifically, on April 10, 2014, Mr. Morehead caused Acuren USA to be in violation of 10 CFR 34.51 and 10 CFR 34.53 by performing industrial radiographic operations without conspicuously posting the area with radiation area and high radiation area signs, and without maintaining continuous direct visual surveillance of the operation to protect against unauthorized entry into a high radiation area.

In a letter dated March 24, 2016 (ADAMS Accession No. ML16085A088), the NRC notified Mr. Morehead of the results of the investigation, informed Mr. Morehead that escalated enforcement action was being considered for an apparent violation, and provided Mr. Morehead the opportunity to attend a predecisional enforcement conference or to participate in an ADR mediation session in an effort to resolve the concern. In response to the NRC's offer, Mr. Morehead requested the use of the NRC's ADR process to resolve differences Mr. Morehead had with the NRC. On June 3, 2016, the NRC and Mr. Morehead met in an ADR session mediated by a professional mediator, arranged through Cornell University's Institute on Conflict Resolution. Alternative dispute resolution is a process in which a neutral mediator, with no decision-making authority, assists the parties in reaching an agreement on resolving any differences regarding the dispute. This Confirmatory Order is issued pursuant to the agreement reached during the ADR process.

III.

During the ADR session, Mr. Morehead and the NRC reached a preliminary settlement agreement. The elements of the agreement recognized corrective actions that Mr. Morehead already completed as described below and included future agreed upon actions as follows:

Corrective actions taken by Mr. Morehead included:

A. Repeated annual refresher training, which included the following topics:

1. Changes to Acuren USA Operating and Emergency Manual.
2. Changes to Federal and State regulations.
3. Department of Transportation requirements and regulation changes.
4. Security Awareness and Emergency Planning.
5. Increased controls and 10 CFR part 37.
6. Violation and incident review.
7. Notification procedures.
8. Radiation surveys and documentation.
9. Equipment maintenance and documentation.
10. As Low As Reasonably Achievable (ALARA) commitment.

B. Successfully completed annual refresher training test for items described in Section A.

C. Completed training and review of the following regulatory documents:

1. 10 CFR parts 19, 20, 21, 30, 34, 37, and 71.
2. New NRC license issued December 17, 2012.
3. ROEM–2011, Revision 1 (Radiographic Operation Emergency Manual).
4. NRC Form 3 (Notice to Employees).
5. Alaska Department of Health and Social Services (DHSS), Radiation Protection.
6. Blank daily radiation reports.
7. Blank Trustworthiness and Reliability (T&R) escort log.
8. Blank exposure device utilization sign out sheet.
9. Shipper's declaration of dangerous goods.

D. Completed Radiographic Personnel Training, which included an examination and follow-up practical demonstrations of the following:

1. Use of an exposure device.
2. Use of personnel monitoring equipment.
3. Use of radiographic survey meters.
4. Performance of daily visual inspections.
5. Demonstration of leak test procedures.
6. Instructions of field audit examinations.

E. Successfully completed training and examination of:

1. "Golden Rules" of radiography.
2. "Buddy Check" systems.
3. Barrier controls.

F. Completed U.S. Department of Transportation, Hazmat, Emergency Planning, and Security Awareness Training.

G. Subjected to and passed additional Acuren USA field audits.

The elements of the agreement, as signed by both parties, consist of the following:

A. The NRC and Mr. Morehead agreed that on April 10, 2014, Mr. Morehead caused Acuren USA to be in violation of 10 CFR 34.51 and 10 CFR 34.53 by performing industrial radiographic operations without conspicuously posting the area with radiation and high radiation area signs and without maintaining continuous direct visual surveillance of the operation to protect against unauthorized entry into a high radiation area. However, the NRC and Mr. Morehead disagree on the deliberate characterization of the violation. More specifically:

1. It is the NRC's view that the preponderance of the evidence supports the proposition that Mr. Morehead deliberately performed industrial radiographic operations without conspicuously posting the area with radiation and high radiation area signs and without maintaining continuous direct visual surveillance of the operation to protect against unauthorized entry into a high radiation area.
2. However, Mr. Morehead disagrees with the deliberate characterization of the violation.

B. Within 12 months of the issuance date of the Confirmatory Order, if supported by Mr. Morehead's employer (currently Acuren USA), Mr. Morehead will provide training to Acuren USA radiographers and radiographer's assistants.

1. Within 30 days before providing the training, Mr. Morehead will submit the training agenda, materials, or content to the Director, Division of Nuclear Materials Safety (DNMS), Region IV.
2. The training (*e.g.*, peer-to-peer, teleconference, etc.) will convey personal lessons learned from the associated issue.

C. Within 18 months of the issuance date of the Confirmatory Order, Mr. Morehead will meet with and observe (*i.e.*, "shadow") a radiation safety officer as the radiation safety officer performs observations of the performance of radiography crews as described in Section 34.43(e)(1) of 10 CFR part 34.

1. Mr. Morehead will perform the field observations of at least four radiographic operations.
2. The observations will be conducted, to the extent possible, without the crew's knowledge.
3. The observations will be conducted at temporary job sites (*i.e.*, "in the field").
4. Mr. Morehead will notify the Director, DNMS, Region IV, prior to the observations. This notification will be made by telephone at 817–200–1106 or email.
5. Within 1 month of the completion of each observation, Mr. Morehead will provide written documentation to the NRC of the date that the observation occurred and the details of the observation (compliances and noncompliances observed, etc.). The information will be sent to the Director, DNMS, 1600 East Lamar Blvd., Arlington, Texas 76011–4511.

D. Within 18 months of the issuance date of the Confirmatory Order, Mr. Morehead will submit an article to an industry publication or to a certifying entity (as defined in 10 CFR 34.3) for publication.

1. The article will convey personal lessons learned from the associated issue and may be co-written with the other radiographer involved with this case.
2. Mr. Morehead will provide the article to the Director, DNMS, Region IV, 30 days prior to the submission of the article.
3. Mr. Morehead will provide to the Director, DNMS, Region IV, demonstration of at least two attempts to publish the article, if publication of the article was not possible.

E. Administrative items.

1. The NRC and Mr. Morehead agree that the above elements will be incorporated into a Confirmatory Order.
2. The NRC will consider the order an escalated enforcement action with respect to any future enforcement actions.
3. In consideration of the commitments delineated above, the NRC will refrain from issuing a Notice of Violation to Mr. Morehead for the violation discussed in NRC Investigation Report 4–2014–043 and NRC Inspection Report 030–38596/2014–001 dated March 24, 2016 (IA–16–025).

On July 8, 2016, Mr. Morehead consented to issuing this Confirmatory Order with the commitments, as described in Section V below. Mr. Morehead further agreed that this Confirmatory Order will be effective upon issuance, the agreement memorialized in this Confirmatory Order settles the matter between the parties, and that Mr. Morehead has waived his right to a hearing.

IV.

I find that Mr. Morehead's commitments as set forth in Section V are acceptable and necessary, and conclude that with these commitments the public health and safety are reasonably assured. In view of the foregoing, I have determined that public health and safety require that Mr. Morehead's commitments be confirmed by this Confirmatory Order. Based on the above and Mr. Morehead's consent, this Confirmatory Order is effective upon issuance.

V.

Accordingly, pursuant to Sections 81, 161b, 161i, 161o, 182, and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR part 30, IT IS HEREBY ORDERED, EFFECTIVE UPON ISSUANCE, THAT:

A. Within 12 months of the issuance date of the Confirmatory Order, if supported by Mr. Morehead's employer (currently Acuren USA), Mr. Morehead will provide training to Acuren USA radiographers and radiographer's assistants.

1. Within 30 days before providing the training, Mr. Morehead will submit the training agenda, materials, or content to the Director, DNMS, Region IV.

2. The training (*e.g.,* peer-to-peer, teleconference, etc.) will convey personal lessons learned from the associated issue.

B. Within 18 months of the issuance date of the Confirmatory Order, Mr. Morehead will meet with and observe (*i.e.,* "shadow") a radiation safety officer as the radiation safety officer performs observations of the performance of radiography crews as described in Section 34.43(e)(1) of 10 CFR part 34.

1. Mr. Morehead will perform the field observations of at least four radiographic operations.

2. The observations will be conducted, to the extent possible, without the crew's knowledge.

3. The observations will be conducted at temporary job sites (*i.e.,* "in the field").

4. Mr. Morehead will notify the Director, DNMS, Region IV, prior to the observations. This notification will be made by telephone at 817–200–1106 or email.

5. Within 1 month of the completion of each observation, Mr. Morehead will provide written documentation to the NRC of the date that the observation occurred and the details of the observation (compliances and noncompliances observed, etc.). The information will be sent to the Director, Division of Nuclear Materials Safety, 1600 East Lamar Blvd., Arlington, Texas 76011–4511.

C. Within 18 months of the issuance date of the Confirmatory Order, Mr. Morehead will submit an article to an industry publication or to a certifying entity (as defined in 10 CFR 34.3) for publication.

1. The article will convey personal lessons learned from the associated issue and may be co-written with the other radiographer involved with this case.

2. Mr. Morehead will provide the article to the Director, DNMS, Region IV, 30 days prior to the submission of the article.

3. Mr. Morehead will provide to the Director, DNMS, Region IV, demonstration of at least two attempts to publish the article, if publication of the article was not possible within the 18 month period.

The Regional Administrator, Region IV, may, in writing, relax or rescind any of the above conditions upon demonstration by Mr. Morehead of good cause.

VI.

In accordance with 10 CFR 2.202 and 10 CFR 2.309, any person adversely affected by this Confirmatory Order, other than Mr. Morehead, may request a hearing within 30 days of the issuance date of this Confirmatory Order. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be directed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and include a statement of good cause for the extension.

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC E-Filing rule (72 FR 49139, August 28, 2007, as amended at 77 FR 46562, August 3, 2012), which is codified in pertinent part at 10 CFR part 2, subpart C. The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten (10) days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at (301) 415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/getting-started.html.* System requirements for accessing the E-Submittal server are detailed in NRC's "Guidance for Electronic Submission," which is available on the agency's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Electronic Filing Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System (EIE), users will be required to install a Web browser plug-in from the NRC Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the agency's adjudicatory E-Filing system may seek assistance by contacting the NRC Electronic Filing Help Desk through the "Contact Us" link located on the NRC's Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email at *MSHD.Resource@nrc.gov,* or by a toll-free call to (866) 672–7640. The NRC Electronic Filing Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket, which is available to the public at *http://ehd1.nrc.gov/ehd/,* unless excluded pursuant to an order of the Commission or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

If a person other than Mr. Morehead requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Confirmatory Order and shall address the criteria set forth in 10 CFR 2.309(d) and (f).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Confirmatory Order should be sustained.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section V above shall be final 30 days from the date of issuance without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section V shall be final when the extension expires if a hearing request has not been received.

For the Nuclear Regulatory Commission.

Dated this 11th day of July 2016.

Kriss M. Kennedy,

Regional Administrator, Region IV.

[FR Doc. 2016–17921 Filed 7–27–16; 8:45 am]

BILLING CODE 7590–01–P

POSTAL SERVICE

Temporary Emergency Committee of the Board of Governors; Sunshine Act Meeting

DATES AND TIMES: Wednesday, August 10, 2016, at 9:30 a.m.

PLACE: Las Vegas, Nevada.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Wednesday, August 10, 2016, at 9:30 a.m.

1. Strategic Issues.
2. Pricing.
3. Financial Matters.
4. Personnel Matters and Compensation Issues.
5. Executive Session—Discussion of prior agenda items and Board governance.

GENERAL COUNSEL CERTIFICATION: The General Counsel of the United States Postal Service has certified that the meeting may be closed under the Government in the Sunshine Act.

CONTACT PERSON FOR MORE INFORMATION: Julie S. Moore, Secretary of the Board, U.S. Postal Service, 475 L'Enfant Plaza SW., Washington, DC 20260–1000. Telephone: (202) 268–4800.

Julie S. Moore.

Secretary.

[FR Doc. 2016–18063 Filed 7–26–16; 4:15 pm]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78396; File No. SR–BATS–2015–100]

Self-Regulatory Organizations; BATS Exchange, Inc.; Order Approving a Proposed Rule Change, as Modified by Amendment No. 6, To Amend BATS Rule 14.11(i) To Adopt Generic Listing Standards for Managed Fund Shares

July 22, 2016.

I. Introduction

On November 18, 2015, BATS Exchange, Inc. (now known as Bats BZX Exchange, Inc., "Exchange" or "BZX") [1] filed with the Securities and Exchange Commission ("Commission"), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act" or "Exchange Act") [2] and Rule 19b–4 thereunder,[3] a proposed rule change to amend Rule 14.11(i) by, among other things, adopting generic listing standards for Managed Fund Shares. The proposed rule change was published for comment in the **Federal Register** on November 25, 2015.[4]

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[1] In March 2016, BATS changed its name from "BATS Exchange, Inc." to "Bats BZX Exchange, Inc." *See* Securities Exchange Act Release No. 77307 (Mar. 7, 2016), 81 FR 12996 (Mar. 11, 2016) (SR–BATS–2016–25) (publishing notice of the name change to Bats BZX Exchange, Inc.).

[2] 15 U.S.C. 78s(b)(1).

On January 4, 2016, the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] On February 9, 2016, the Exchange filed Amendment No. 1 to the proposed rule change, which replaced the originally filed proposed rule change in its entirety. On February 11, 2016, the Exchange both filed and withdrew Amendment No. 2 to the proposed rule change. On February 11, 2016, the Exchange also filed Amendment No. 3 to the proposed rule change.[6] On February 17, 2016, the Exchange filed Amendment No. 4 to the proposed rule change.[7]

On February 22, 2016, the Commission issued notice of filing of Amendments No. 1, 3, and 4 to the proposed rule change and instituted proceedings under section 19(b)(2)(B) of the Act[8] to determine whether to approve or disapprove the proposed rule change, as modified by Amendments No. 1, 3, and 4.[9] In the Order Instituting Proceedings, the Commission solicited comments to specified matters related to the proposal.[10] On May 20, 2016, the Commission designated a longer period for Commission action on the proposed rule change.[11]

On June 3, 2016, the Exchange filed Amendment No. 5 to the proposed rule change, which replaced Amendment No. 1 (as further modified by Amendments No. 3 & 4) to the proposed rule change.[12] The Commission issued a notice of the filing of Amendment No. 5 on June 7, 2016 and solicited comments on the modified proposal.[13] On July 21, 2016, the Exchange filed Amendment No. 6 to the proposed rule change,[14] which amended and replaced the Amendment No. 5 to the proposed rule change.

The Commission has not received any comments on the proposed rule change, as modified by Amendment No. 5. This order approves the proposed rule change, as modified by Amendment No. 6.

II. Description of the Proposal, as Modified by Amendment No. 6

BATS Rule 14.11(i) governs the listing and trading of Managed Fund Shares on the Exchange. Managed Fund Shares are issued by exchange-traded funds ("ETFs") that are actively managed and do not seek to replicate the performance of a specified index of securities.

Under its current rules, the Exchange must file separate proposals under section 19(b) of the Act before listing a new series of Managed Fund Shares.[15] The Exchange proposes to adopt generic listing standards so that the Exchange may list Managed Fund Shares that satisfy the applicable criteria by submitting notice pursuant to Rule 19b–4(e) under the Act, rather than by filing a proposed rule change under section 19(b).[16]

A. The Proposed Generic Listing Standards

The Exchange's proposed listing standards establish requirements for the various types of assets that may be held in the portfolio of a generically listed, actively managed ETF ("Portfolio").

1. Equity Portfolio Components

Proposed BATS Rule 14.11(i)(4)(C)(i) establishes the criteria applicable to the equity securities included in a Portfolio. Equity securities include the following securities: U.S. Component Stocks, which are defined in BATS Rule 14.11(c)(1)(D); Non-U.S. Component Stocks, which are defined in BATS Rule 14.11(c)(1)(E); Derivative Securities Products, which are defined in BATS Rule 14.11(c)(3)(A)(i)(a); Linked

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[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 76478 (Nov. 19, 2015), 80 FR 73841.

[5] *See* Securities Exchange Act Release No. 76820, 81 FR 989 (Jan. 8, 2016). The Commission designated February 23, 2016 as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change. *See id.*

[6] Amendment No. 3 deletes from the proposal the following two statements: (1) "Such limitation will not apply to listed swaps because swaps are listed on swap execution facilities ("SEFs"), the majority of which are not members of ISG[;]" and (2) "Such limitation would not apply to listed swaps because swaps are listed on SEFs, the majority of which are not members of ISG." Amendment No. 3 also corrects an erroneous statement in Item 11 to indicate that an Exhibit 4 was included in Amendment No. 1. Amendment No. 3 is available at: *http://www.sec.gov/comments/sr-bats-2015-100/bats2015100-3.pdf.*

[7] Amendment No. 4 deletes from the proposal the following sentence: "Thus, if the limitation applied to swaps, there would effectively be a cap of 10% of the portfolio invested in listed swaps." Amendment No. 4 also amends two representations as follows (*added* language in brackets): The Exchange or FINRA, on behalf of the Exchange, will communicate as needed regarding trading in Managed Fund Shares [and their underlying components] with other markets that are members of the ISG, including all U.S. securities exchanges and futures exchanges on which the components are traded[, or with which the Exchange has in place a CSSA.] In addition, the Exchange or FINRA[,] on behalf of the Exchange[,] may obtain information regarding trading in Managed Fund Shares [and their underlying components] from other markets that are members of the ISG, including all U.S. securities exchanges and futures exchanges on which the components are traded, or with which the Exchange has in place a CSSA." Amendment No. 4 is available at: *http://www.sec.gov/comments/sr-bats-2015-100/bats2015100-4.pdf.*

[8] 15 U.S.C. 78s(b)(2)(B).

[9] *See* Securities Exchange Act Release No. 77202, 81 FR 9889 (Feb. 26, 2016) ("Order Instituting Proceedings"). Specifically, the Commission instituted proceedings to allow for additional analysis of the proposed rule change's consistency with section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be "designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade," and "to protect investors and the public interest." *See id.*, 81 FR at 9897.

[10] *See id.*

[11] *See* Securities Exchange Act Release No. 77871, 81 FR 33567 (May 26, 2016) (designating July 22, 2016 as the date by which the Commission must either approve or disapprove the proposed rule change).

[12] *See* Securities Exchange Act Release No. 78005, 81 FR 38247, 38248 (June 13, 2016) ("Notice"). Amendment No. 5 is available at: *http://www.sec.gov/comments/sr-bats-2015-100/bats2015100-5.pdf.*

[13] *See Notice, supra* note 12.

[14] In Amendment No. 6, the Exchange added the following representations: (1) On a periodic basis, and no less than annually, the Exchange will review the Managed Fund Shares generically listed and traded on the Exchange under BATS Rule 14.11(i) for compliance with that rule and will provide a report to its Regulatory Oversight Committee presenting the findings of its review; and (2) on a quarterly basis, the Exchange will provide a report to the Commission staff that contains, for each ETF whose shares are generically listed and traded under BATS Rule 14.11(i): (a) Symbol and date of listing; (b) the number of active authorized participants ("APs") and a description of any failure by either a fund or an AP to deliver promised baskets of shares, cash, or cash and instruments in connection with creation or redemption orders; and (c) a description of any failure by an ETF to comply with BATS Rule 14.11(i). The Exchange also modified proposed BATS Rule 14.11(i)(4)(C) to read: "The Exchange may approve Managed Fund Shares for listing pursuant to Rule 19b–4(e) under the Act. Components of a series of Managed Fund Shares listed pursuant to Rule 19b–4(e) shall satisfy the criteria set forth within this Rule 14.11(i) upon initial listing and on a continual basis. The Exchange will file separate proposals under Section 19(b) of the Act before the listing and trading of a series of Managed Fund Shares with components that do not satisfy the criteria set forth within this Rule 14.11(i) or components other than those specified below." In the Commission's view, the changes to proposed rule text of Rule 14.11(i)(4)(C) are not substantive. Amendment No. 6 is available at: *https://www.sec.gov/comments/sr-bats-2015-100/bats2015100-6.pdf.* Because Amendment No. 6 does not materially alter the substance of the proposed rule change or raise unique or novel regulatory issues, Amendment No. 6 is not subject to notice and comment.

[15] *See* BATS Rule 14.11(i)(2)(A).

[16] 17 CFR 240.19b–4(e). Rule 19b–4(e) permits self-regulatory organizations to list and trade new derivatives products that comply with existing SRO trading rules, procedures, surveillance programs and listing standards, without submitting a proposed rule change under Section 19(b). *See* Securities Exchange Act Release No. 40761 (Dec. 8, 1998), 63 FR 70952 (Dec. 22, 1998).

Securities, which are securities eligible for listing on the Exchange under BATS Rule 14.11(d), and each of the equivalent security types listed on another national securities exchange. Additionally, proposed Rule 14.11(i)(4)(C)(i) provides that no more than 25% of the equity weight of the Portfolio can include leveraged or inverse-leveraged Derivative Securities Products or Linked Securities and that, to the extent a Portfolio includes convertible securities, the equity securities into which such securities are converted must meet the criteria of this Rule 14.11(i)(4)(C)(i) after converting.

Proposed BATS Rule 14.11(i)(4)(C)(i)(a) would require that U.S. Component Stocks (except as mentioned below) meet the following criteria initially and on a continuing basis:

(1) Component stocks (excluding Derivative Securities Products and Linked Securities) that in the aggregate account for at least 90% of the equity weight of the Portfolio (excluding Derivative Securities Products and Linked Securities) each shall have a minimum market value of at least $75 million;

(2) component stocks (excluding Derivative Securities Products and Linked Securities) that in the aggregate account for at least 70% of the equity weight of the Portfolio (excluding Derivative Securities Products and Linked Securities) each shall have a minimum monthly trading volume of 250,000 shares, or minimum notional volume traded per month of $25,000,000, averaged over the previous six months;

(3) the most heavily weighted component stock (excluding Derivative Securities Products and Linked Securities) must not exceed 30% of the equity weight of the Portfolio, and, to the extent applicable, the five most heavily weighted component stocks (excluding Derivative Securities Products and Linked Securities) must not exceed 65% of the equity weight of the Portfolio;

(4) where the equity portion of the Portfolio does not include Non-U.S. Component Stocks, the equity portion of the Portfolio shall include a minimum of 13 component stocks; provided, however, that there would be no minimum number of component stocks if (a) one or more series of Derivative Securities Products or Linked Securities constitute, at least in part, components underlying a series of Managed Fund Shares, or (b) one or more series of Derivative Securities Products or Linked Securities account for 100% of the equity weight of the Portfolio of a series of Managed Fund Shares;

(5) except as provided in proposed BATS Rule 14.11(i)(4)(C)(i)(a), equity securities in the Portfolio must be U.S. Component Stocks listed on a national securities exchange and must be NMS Stocks as defined in Rule 600 of Regulation NMS; and

(6) American Depositary Receipts (''ADRs'') may be exchange traded or non-exchange traded, but no more than 10% of the equity weight of the Portfolio shall consist of non-exchange traded ADRs.

Proposed BATS Rule 14.11(i)(4)(C)(i)(b) requires that Non-U.S. Component Stocks must meet the following criteria initially and on a continuing basis:

(1) Non-U.S. Component Stocks each shall have a minimum market value of at least $100 million;

(2) Non-U.S. Component Stocks each shall have a minimum global monthly trading volume of 250,000 shares, or minimum global notional volume traded per month of $25,000,000, averaged over the last six months;

(3) the most heavily weighted Non-U.S. Component Stock shall not exceed 25% of the equity weight of the Portfolio, and, to the extent applicable, the five most heavily weighted Non-U.S. Component Stocks shall not exceed 60% of the equity weight of the Portfolio;

(4) where the equity portion of the Portfolio includes Non-U.S. Component Stocks, the equity portion of the Portfolio shall include a minimum of 20 component stocks; provided, however, that there shall be no minimum number of component stocks if (a) one or more series of Derivative Securities Products or Linked Securities constitute, at least in part, components underlying a series of Managed Fund Shares, or (b) one or more series of Derivative Securities Products or Linked Securities account for 100% of the equity weight of the Portfolio of a series of Managed Fund Shares; and

(5) each Non-U.S. Component Stock shall be listed and traded on an exchange that has last-sale reporting.

2. Fixed Income Portfolio Components

Proposed BATS Rule 14.11(i)(4)(C)(ii) establishes criteria for fixed income securities that are included in a Portfolio. Fixed income securities are debt securities[17] that are notes, bonds, debentures, or evidence of indebtedness that include, but are not limited to, U.S. Department of Treasury securities (''Treasury Securities''), government-sponsored entity securities (''GSE Securities''), municipal securities, trust preferred securities, supranational debt and debt of a foreign country or a subdivision thereof, investment grade and high yield corporate debt, bank loans, mortgage and asset backed securities, and commercial paper.[18] To the extent that a Portfolio includes convertible securities, the fixed income securities into which such securities are converted shall meet the criteria of proposed BATS Rule 14.11(i)(4)(C)(ii) after converting.[19] Under proposed BATS Rule 14.11(i)(4)(C)(ii), fixed income securities that are part of a Portfolio must satisfy the following criteria initially and on a continuing basis:

(1) Components that in the aggregate account for at least 75% of the fixed income weight of the Portfolio must each have a minimum original principal amount outstanding of $100 million or more;

(2) no component fixed-income security (excluding Treasury Securities and GSE Securities) shall represent more than 30% of the fixed income weight of the Portfolio, and the five most heavily weighted fixed income securities in the Portfolio (excluding Treasury Securities and GSE Securities) shall not in the aggregate account for more than 65% of the fixed income weight of the Portfolio;

(3) a Portfolio that includes fixed income securities (excluding exempted securities) shall include a minimum of 13 non-affiliated issuers, provided, however, that there shall be no minimum number of non-affiliated issuers required for fixed income securities if at least 70% of the weight of the Portfolio consists of equity securities as described in BATS Rule 14.11(i)(4)(C)(i);

(4) Component securities that in aggregate account for at least 90% of the fixed income weight of the Portfolio must be: (a) From issuers that are required to file reports pursuant to sections 13 and 15(d) of the Act; (b) from issuers each of which has a worldwide market value of its outstanding common equity held by non-affiliates of $700 million or more; (c) from issuers each of which has outstanding securities that are notes,

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[17] Debt securities include a variety of fixed income obligations, including, but not limited to, corporate debt securities, government securities, municipal securities, convertible securities, and mortgage-backed securities. Debt securities include investment-grade securities, non-investment-grade securities, and unrated securities. Debt securities also include variable and floating rate securities. *See* Amendment No. 6, *supra* note 14, at 52, n.27.

[18] *See* proposed BATS Rule 14.11(i)(4)(C)(ii).

[19] *See id.*

bonds, debentures, or evidence of indebtedness having a total remaining principal amount of at least $1 billion; (d) exempted securities as defined in section 3(a)(12) of the Act; or (e) from issuers that are a government of a foreign country or a political subdivision of a foreign country; and

(5) non-agency, non-GSE, and privately issued mortgage-related and other asset-backed securities shall not account, in the aggregate, for more than 20% of the weight of the fixed income portion of the Portfolio.

3. Cash and Cash Equivalents in Portfolios

Proposed BATS Rule 14.11(i)(4)(C)(iii) provides that a Portfolio may include cash and cash equivalents. Cash equivalents are defined as short-term instruments with maturities of less than 3 months.[20] The Exchange defines short-term instruments to include the following: (1) U.S. Government securities, including bills, notes and bonds differing as to maturity and rates of interest, which are either issued or guaranteed by the U.S. Treasury or by U.S. Government agencies or instrumentalities; (2) certificates of deposit issued against funds deposited in a bank or savings and loan association; (3) bankers' acceptances, which are short-term credit instruments used to finance commercial transactions; (4) repurchase agreements and reverse repurchase agreements; (5) bank time deposits, which are monies kept on deposit with banks or savings and loan associations for a stated period of time at a fixed rate of interest; (6) commercial paper, which are short-term unsecured promissory notes; and (7) money market funds.[21] BATS does not propose to limit to the amount of cash or cash equivalents that may be held in a Portfolio.[22]

4. Derivative Portfolio Components

Proposed BATS Rule 14.11(i)(4)(C)(iv) establishes listing criteria for the portion of a Portfolio that consists of listed derivatives such as futures, options, and swaps overlying commodities, currencies, financial instruments (*e.g.,* stocks, fixed income securities, interest rates, and volatility), or a basket or index of any of the foregoing. The Exchange does not propose to limit the percentage of a Portfolio that may be composed of such holdings, *provided that,* in the aggregate, at least 90% of the weight of holdings in listed derivatives (calculated using the aggregate gross notional value) must, on both an initial and continuing basis, consist of futures, options, and swaps for which the Exchange may obtain information via the ISG from other members or affiliates or for which the principal market is a market with which the Exchange has a comprehensive surveillance sharing agreement ("CSSA").[23] Additionally, the aggregate gross notional value of listed derivatives based on any five or fewer underlying reference assets shall not exceed 65% of the weight of the Portfolio (including gross notional exposures), and the aggregate gross notional value of listed derivatives based on any single underlying reference asset shall not exceed 30% of the weight of the Portfolio (including gross notional exposures).[24]

Proposed BATS Rule 14.11(i)(4)(C)(v) establishes a limit on OTC derivatives: No more than 20% of the weight of the Portfolio may be invested in OTC derivatives.[25] The Exchange notes that, for purposes of calculation this limitation, a portfolio's investment in OTC derivatives will be calculated as the aggregate gross notional value of the OTC derivatives.

Proposed BATS Rule 14.11(i)(4)(C)(vi) provides that, to the extent that listed or OTC derivatives are used to gain exposure to individual equities and/or fixed income securities, or to indexes of equities and/or fixed income securities, the aggregate gross notional value of such exposure shall meet the criteria set forth in proposed BATS Rules 14.11(i)(4)(C)(i) and 14.11(i)(4)(C)(ii), respectively.

B. Other Aspects of the Proposal

1. Disclosed Portfolio

The daily dissemination of a Disclosed Portfolio[26] is required under current BATS Rule 14.11(i)(4)(B)(ii)(a), but its contents are not specified. The Exchange proposes to amend the definition of "Disclosed Portfolio" to require that the Web site for each series of Managed Fund Shares listed on the Exchange, including all Managed Fund Shares currently listed and traded on the Exchange, disclose the following information in the Disclosed Portfolio, to the extent applicable: Ticker symbol, CUSIP or other identifier, a description of the holding, identity of the asset upon which the derivative is based, the strike price for any options, the quantity of each security or other asset held as measured by select metrics, maturity date, coupon rate, effective date, market value, and percentage weight of the holding in the portfolio.

2. Investment Objective

The Exchange proposes to add as an initial listing criterion applicable to all Managed Fund Shares (including those that are generically listed) the requirement that Managed Fund Shares must have a stated investment objective, which shall be adhered to under "Normal Market Conditions."[27] The Exchange would define "Normal Market Conditions" as circumstances including, but not limited to the absence of: Trading halts in the applicable financial markets generally; operational issues causing dissemination of inaccurate market information or systems failure; or *force majeure* type events such as natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption, or any similar intervening circumstance.[28]

3. Intraday Indicative Value ("IIV")

The Exchange proposes to modify a continued listing criterion for *all* Managed Fund Shares to require that the IIV be widely disseminated by one or more major market data vendors at least every 15 seconds during Regular Trading Hours, as defined in BATS Rule 1.5(w),[29] rather than during all times that Managed Fund Shares trade on the Exchange.

C. Additional Representations of the Exchange Applicable to the Listing and Trading of Managed Fund Shares

In support of the proposed rule change, the Exchange represents that:

(1) Generically listed Managed Fund Shares will conform to the initial and continued listing criteria under Rule 14.11(i)(4)(A) and (B).[30]

(2) The Exchange's surveillance procedures are adequate to continue to properly monitor the trading of the Managed Fund Shares in all trading sessions and to deter and detect violations of Exchange rules. Specifically, the Exchange intends to utilize its existing surveillance procedures applicable to derivative

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[20] *See* proposed BATS Rule 14.11(i)(4)(C)(iii).

[21] *See* proposed BATS Rule 14.11(i)(4)(C)(iii)(b).

[22] *See* proposed BATS Rule 14.11(i)(4)(C)(iii)(a).

[23] *See* proposed BATS Rule 14.11(i)(4)(C)(iv)(a).

[24] *See* proposed BATS Rule 14.11(i)(4)(C)(iv)(b).

[25] OTC derivatives include: Forwards, options, and swaps overlying commodities, currencies, financial instruments (*e.g.,* stocks, fixed income securities, interest rates, and volatility), or a basket or index of any of the foregoing. *See* proposed BATS Rule 14.11(i)(4)(C)(v).

[26] BATS defines "Disclosed Portfolio" for purposes of its Managed Fund Shares listing rule as the identities and quantities of the securities and other assets held by the Investment Company that will form the basis for the Investment Company's calculation of net asset value at the end of the business day. *See* BATS Rule 14.11(i)(3)(B).

[27] *See* proposed BATS Rule 14.11(i)(4)(A)(iii).

[28] *See* proposed BATS Rule 14.11(i)(3)(E).

[29] *See* proposed BATS Rule 14.11(i)(4)(B)(i).

[30] *See* Amendment No. 6, *supra* note 14, at 24.

products, which will include Managed Fund Shares, to monitor trading in the Managed Fund Shares.[31]

(3) Prior to the commencement of trading of a particular series of Managed Fund Shares, the Exchange will inform its Members in an information circular of the special characteristics and risks associated with trading the Managed Fund Shares, including procedures for purchases and redemptions of Managed Fund Shares, suitability requirements under Rule 3.7, the risks involved in trading the Managed Fund Shares during the Pre-Opening and After Hours Trading Sessions when an updated IIV will not be calculated or publicly disseminated, how information regarding the IIV and Disclosed Portfolio is disseminated, prospectus delivery requirements, and other trading information. In addition, the information circular will disclose that the Managed Fund Shares are subject to various fees and expenses, as described in the registration statement, and will discuss any exemptive, no-action, and interpretive relief granted by the Commission from any rules under the Act. Finally, the Bulletin will disclose that the NAV for the Managed Fund Shares will be calculated after 4 p.m. ET each trading day.[32]

(4) The issuer of a series of Managed Fund Shares will be required to comply with Rule 10A–3 under the Act for the initial and continued listing of Managed Fund Shares, as provided under Rule 14.10(c)(3).[33]

(5) BATS has represented that: (1) On a periodic basis, and no less than annually, the Exchange will review the Managed Fund Shares generically listed and traded on the Exchange under BATS Rule 14.11(i) for compliance with that rule and will provide a report to its Regulatory Oversight Committee presenting the findings of its review; and (2) on a quarterly basis, the Exchange will provide a report to the Commission staff that contains, for each ETF whose shares are generically listed and traded under BATS Rule 14.11(i): (a) Symbol and date of listing; (b) the number of active authorized participants ("APs") and a description of any failure by either a fund or an AP to deliver promised baskets of shares, cash, or cash and instruments in connection with creation or redemption orders; and (c) a description of any failure by an ETF to comply with BATS Rule 14.11(i).[34]

(6) Prior to listing pursuant to proposed amended Rule 14.11(i), an issuer would be required to represent to the Exchange that it will advise the Exchange of any failure by a series of Managed Fund Shares to comply with the continued listing requirements, and, pursuant to its obligations under section 19(g)(1) of the Exchange Act, the Exchange will surveil for compliance with the continued listing requirements. If a series of Managed Fund Shares is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under Exchange Rule 14.12.[35]

III. Discussion and Commission Findings

After careful review, the Commission finds that the Exchange's proposal to amend its Rule 14.11(i) to, among other things, adopt generic listing criteria, is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange.[36] In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 6, is consistent with section 6(b)(5) of the Act,[37] which requires, among other things, that the Exchange's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

In support of its proposal, the Exchange states that its proposed requirements for Managed Fund Shares are based in large part on the generic listing criteria currently applicable to Index Fund Shares.[38] As a general matter, the Commission believes that this is an appropriate approach with respect to underlying asset classes covered by the existing generic standards, because the mere addition of active management to an ETF portfolio that would qualify for generic listing as an index-based ETF should not affect the portfolio's susceptibility to manipulation or the availability of arbitrage between the ETF and its underlying portfolio. Below, the Commission addresses the proposed criteria for each of the asset classes encompassed within the generic listing standards.

Equity Holdings. With respect to the equity holdings of a Portfolio, the proposed criteria closely track the existing standards for Index Fund Shares, with four relevant differences. First, while the generic listing criteria for Index Fund Shares do not permit the inclusion of any non-exchange-traded ADRs in the underlying index,[39] the proposed generic criteria for Managed Fund Shares would permit an ETF to hold up to 10% of the equity weight of the Portfolio in non-exchange-traded ADRs. This proposed provision, however, is consistent with standards that the Commission has approved for specific ETFs listed and traded as Managed Fund Shares.[40] Moreover, the Commission believes that the proposed requirement that at least 90% of the equity portion of a Portfolio consist of domestic equity securities (a category that includes ADRs) for which the Exchange may obtain transaction data should both deter manipulation of generically listed Managed Fund Shares and permit the Exchange to investigate any instances of manipulation.

Second, the proposed standards would differ slightly from the existing generic standards for Index Fund Shares with respect to Non-U.S. Component Stocks. The proposed standards would provide that *all* Non-U.S. Component Stocks in a Portfolio must have a minimum market value of at least $100 million. By contrast, the generic listing criterion for Index Fund Shares requires only 90% of the Non-U.S. Component Stocks (excluding Derivative Securities Products) included in an index to meet the same minimum market-value threshold.[41] Additionally, under the proposal, *all* Non-U.S. Component Stocks included in a Portfolio must have a minimum global monthly trading volume of 250,000 shares, or minimum global notional volume traded per month of $25,000,000, averaged over the previous six months.[42] By contrast, only 70% of the weight of an index (excluding Derivative Securities

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[31] *See id.* at 24–25.

[32] *See id.* at 25.

[33] *See id.*

[34] *See id.* at 25–26.

[35] *See id.* at 27–28.

[36] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[37] 15 U.S.C. 78f(b)(5).

[38] *See* Amendment No. 6, *supra* note 14, at 63.

[39] The Commission notes, however, that a portfolio underlying Index Fund Shares nevertheless may contain non-exchange-listed ADRs because the portfolio need not consist only of index components.

[40] *See, e.g.,* Securities Exchange Act Release No. 72679 (July 28, 2014), 79 FR 44878 (Aug. 1, 2014) (SR–NYSEArca–2014–71); Securities Exchange Act Release No. 67277 (June 27, 2012), 77 FR 39554 (July 3, 2012) (SR–NYSEArca–2012–39).

[41] *See* BATS Rule 14.11(c)(A)(3)(ii)(a).

[42] The Commission approved a listing rule that contained these heightened market capitalization and trading volume requirements. *See* Securities Exchange Act Release No. 75023 (May 21, 2015), 80 FR 30519 (May 28, 2015) (SR–NYSEArca–2014–100).

Products) underlying generically listed Index Fund Shares must satisfy the same monthly volume thresholds.[43] The Commission believes that the proposed provisions should reduce the extent to which Managed Fund Shares holding Non-U.S. Component Stocks may be susceptible to manipulation.

Third, while the Exchange's existing generic listing standards for index-based ETFs do not apply concentration limits to an index's exposure to specified exchange-traded products (called "Derivative Securities Products"), which have concentration limits or price transparency requirements within their own listing standards, proposed BATS Rule 14.11(i)(4)(C)(ii) would also deem Portfolio concentration limits not to apply to holdings of specified exchange-traded notes (called "Linked Securities"). The Commission believes that this change should not increase the susceptibility of Managed Fund Shares to manipulation because Linked Securities, like Derivative Securities Products, have asset-exposure concentration limits and requirements promoting price transparency within their own listing standards, and both Derivative Securities Products and Linked Securities are listed and traded on national securities exchanges (which are all members of ISG), publicly provide information about listed Derivative Securities Products and Linked Securities, and provide trading and price information and other quantitative date for investors and other market participants.

And fourth, under current generic listing standards, index-based ETFs cannot seek inverse returns greater than 300% of the performance of their reference index, and there is no limit on positive leverage versus an index. By contrast, the proposed standards would impose an absolute cap—25%—on the amount of an ETF's portfolio that could be invested in leveraged or inverse-leveraged ETPs. The Commission believes that a limitation on the overall use of leveraged ETFs is consistent with section 6(b)(5) of the Act because it will limit the extent to which the performance of a generically listed, actively managed ETF can be tied to a product whose performance over periods of longer than one day can differ significantly from its stated daily performance objective.[44]

Fixed Income Holdings. With respect to the fixed income components of a Portfolio, the standards proposed by the Exchange are based in large part on the standards in BATS Rule 14.11(c)(4) for the components of fixed income indexes underlying Index Fund Shares, with three relevant differences. First, proposed BATS Rule 14.11(i)(4)(C)(ii)(c) does not require a minimum number of non-affiliated issuers for fixed income securities in the portfolio if at least 70% of the weight of the portfolio consists of equity securities as set forth in BATS Rule 14.11(i)(4)(C)(i). Second, proposed BATS Rule 14.11(i)(4)(C)(ii)(e) would prohibit non-agency, non-GSE, and privately issued mortgage-related and other asset-backed securities components of a Portfolio from constituting, in the aggregate, more than 20% of the weight of the fixed income portion of the Portfolio.[45] And third, The proposed standards would make explicit that convertible bonds would both (a) have to meet the criteria for fixed-income holdings and (b) be convertible into equities that would meet the criteria for equity holdings.

The Commission believes that, taken together, the proposed requirements for the fixed income portion of a Portfolio are reasonably designed to ensure that a substantial portion of a Portfolio consists of fixed income securities for which information is publicly available and, when applied in conjunction with the other applicable listing requirements, will permit the listing and trading only of Managed Fund Shares that are sufficiently broad-based to minimize the potential for manipulation. The Commission also believes that these provisions should help ensure that the fixed income portion of a Portfolio consists of assets for which available intra-day values allow market participants to identify and capitalize upon arbitrage opportunities, which in turn should help keep the intra-day prices of generically listed Managed Fund Shares reasonably aligned with the intra-day values of their underlying assets.

Cash and Cash Equivalents. With respect to cash and cash equivalents to be held in a Portfolio, the Commission believes that the proposed standards appropriately define the type of short-term instruments that would qualify as such holdings.

Derivatives Holdings. With respect to derivatives of any type included in a Portfolio, proposed BATS Rule 14.11(i)(4)(C)(vi) provides that, to the extent they are used to gain exposure to individual equities or fixed income securities, or to indexes of equities or fixed income securities, the total notional exposure to the underlying instruments—whether achieved through cash instruments or derivative instruments—must meet the numerical and other criteria set forth in proposed BATS Rule 14.11(i)(4)(C)(i) and 14.11(i)(4)(C)(ii), as applicable. The Commission believes that this provision should make Portfolios less susceptible to manipulation by preventing circumvention of the quantitative and other requirements applicable to equity and fixed income security components of a Portfolio.

With respect to listed derivatives, the proposal would allow a generically listed ETF to use listed derivatives to achieve 100% of its Portfolio exposure, provided that, in the aggregate, at least 90% of the weight of holdings in futures, exchange-traded options, and listed swaps consists of futures, options, and swaps for which: (1) The Exchange may obtain information from other ISG members or affiliate members; or (2) the principal market is a market with which the Exchange has a CSSA.[46] Additionally, BATS represents that it (or FINRA on its behalf) will communicate regarding, and obtain trade information as needed for, the underlying exchange-listed instruments whose principal market is either an ISG member or a market with which BATS has a CSSA.[47] The Commission believes that these provisions should both deter potential manipulation and permit BATS to investigate suspected manipulation of generically listed Managed Fund Shares that use listed derivatives. Additionally, the Commission believes that the price transparency of listed derivatives should enable market participants to identify and execute arbitrage strategies that will tend to equalize the market price of generically listed Managed Fund Shares with the value of the underlying Portfolios. The Commission also notes that proposed BATS Rule 14.11(i)(4)(C)(iv)(b) imposes concentration limits on the use of listed derivatives. The Commission believes that this limitation should make Portfolios that contain listed derivatives less susceptible to manipulation.

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[43] *See* BATS Rule 14.11(c)(A)(3)(ii)(b).

[44] *Cf.* SEC Invester Alert, Leveraged and Inverse ETFs: Specialized Products with Extra Risks for Buy-and-Hold Investors, available at *https://www.sec.gov/investor/pubs/leveragedetfs-alert.htm.*

[45] The Commission notes that it has approved listing and trading rules for specific ETFs listed as Managed Fund Shares that limit holdings of non-agency asset-backed securities to 20% of the value of the fund's portfolio. *See, e.g.,* Securities Exchange Act Release No. 74297 (Feb. 18, 2015), 80 FR 9788 (Feb. 24, 2015) (SR–BATS–2014–056); Securities Exchange Act Release No. 75566 (July 30, 2015), 80 FR 46612 (Aug. 5, 2015) (SR–NYSEArca–2015–42).

[46] *See* Amendment No. 6, *supra* note 14, at 66. The Exchange also states that: (1) A fund's investments in derivatives, including listed derivatives, would be subject to limits on leverage imposed by the Investment Company Act of 1940, 15 U.S.C. 80a–1 ("1940 Act"); (2) to limit the potential risk associated with a fund's use of derivatives, a fund will segregate or "earmark" assets determined to be liquid by a fund in accordance with the 1940 Act (or, as permitted by applicable regulation, enter into certain offsetting positions) to cover its obligations under derivative instruments; (3) a fund's investments will not be used to seek performance that is the multiple or inverse multiple (*i.e.,* 2Xs or 3Xs) of a fund's broad-based securities market index (as defined in Form N–1A). *See id.* at 70.

[47] *See id.* at 72.

With respect to OTC derivatives, proposed BATS Rule 14.11(i)(4)(C)(v) would permit a Portfolio to include OTC derivatives, but would limit the amount of such derivatives to 20% of the fund's assets, thereby ensuring that the preponderance of a fund's investments would not be in derivatives that are not listed and centrally cleared. The Commission believes that this limit is sufficient to mitigate the risks associated with price manipulation because at least 80% of a Portfolio would consist of: Cash and cash equivalents; listed derivatives, of which 90% by portfolio weight would be traded on a principal market that is a member of ISG; and equity securities or fixed income instruments subject to numerous restrictions designed to prevent manipulation and ensure pricing transparency.

The Commission notes that, in addition to proposing the listing criteria described above for specific asset classes, the Exchange has committed to conduct an ongoing compliance review of the ETFs that are generically listed as Managed Fund Shares. Specifically, the Exchange has represented that, no less than annually, it will review the Managed Fund Shares generically listed and traded on the Exchange under BATS Rule 14.11(i) for compliance with that rule and will provide a report to its Regulatory Oversight Committee presenting the findings of its review. The Exchange has also committed to provide, on a quarterly basis, a report to the Commission staff that contains, for each ETF whose shares are generically listed and traded under BATS Rule 14.11(i): (a) The symbol and date of listing; (b) the number of active APs and a description of any failure by either a fund or an AP to deliver promised baskets of shares, cash, or cash and instruments in connection with creation or redemption orders; and (c) a description of any failure by an ETF to comply with BATS Rule 14.11(i).[48] The Commission believes that the quarterly report provided by the Exchange will assist the Commission in using public data to review the trading characteristics of ETFs listed under these generic standards.[49]

The Commission also notes that, prior to listing pursuant to BATS Rule 14.11(i), an issuer would be required to represent to the Exchange that it will advise the Exchange of any failure by a series of Managed Fund Shares to comply with the continued listing requirements, and, pursuant to its obligations under section 19(g)(1) of the Act, the Exchange will surveil for compliance with the continued listing requirements. If a series of Managed Fund Shares is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under Exchange Rule 14.12.[50]

The Commission believes that the proposed generic listing criteria, taken together, should promote the listing only of Managed Fund Shares that are not susceptible to manipulation. Additionally, the proposed generic listing standards as a whole should ensure that Portfolios are composed predominantly of instruments for which available intra-day values allow market participants to identify and capitalize upon arbitrage opportunities, which in turn should help keep the intra-day prices of generically listed Managed Fund Shares reasonably aligned with the intra-day values of their underlying assets.

For the reasons discussed above, the Commission finds that the proposed generic listing standards for Managed Fund Shares are consistent with section 6(b)(5) of the Act.[51]

In addition, BATS proposes changes to Rule 14.11(i) that apply to *all* Managed Fund Shares (*i.e.,* both funds listed generically under the proposed standards and funds listed pursuant to individual 19b–4 filings by the Exchange). Specifically, the Exchange proposes to specify the information that must be included in the Disclosed Portfolio disseminated by each actively managed ETF. Previously approved listing rules for specific ETFs listed as Managed Fund Shares have included identical disclosure requirements.[52] The mandatory disclosures include information that market participants can use to value an actively managed ETF's holdings intra-day, which should facilitate arbitrage opportunities that should help keep the intra-day prices of Managed Fund Shares reasonably aligned with the intra-day values of their underlying assets.

The Exchange also proposes to amend the continued listing requirement in BATS Rule 14.11(i)(4)(B)(i), which is applicable to all Managed Fund Shares, to require dissemination of an IIV at least every 15 seconds during Regular Trading Hours, as defined in BATS Rule 1.5(w). The Exchange states that this requirement would be consistent with the IIV dissemination requirement for Index Fund Shares as well as representations made in support of approved proposals to list and trade shares of specific ETFs listed and traded as Managed Fund Shares.[53] The Commission also notes that the IIV dissemination during Regular Trading Hours is also required for all Managed Trust Securities.[54]

Finally, the Exchange proposes to add as an initial listing criterion applicable to all Managed Fund Shares (including those that are generically listed) the requirement that Managed Fund Shares must have a stated investment objective, which shall be adhered to under "Normal Market Conditions," defined as circumstances including, but not limited to, the absence of: Trading halts in the applicable financial markets generally; operational issues causing dissemination of inaccurate market information or systems failure; or *force majeure* type events such as natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption, or any similar intervening circumstance.[55] The Commission believes that this proposed change is consistent with previous Commission approvals of specific ETFs listed as Managed Fund Shares.

For the foregoing reasons, the Commission finds that the proposed rule change, as modified by Amendment No. 6, is consistent with section 6(b)(5) of the Act[56] and the rules and regulations thereunder applicable to a national securities exchange.

IV. Conclusion

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[57] that the proposed rule change (SR–BATS–2015–

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[48] *See id.* at 25–26.

[49] The Commission also notes that all Managed Fund Shares listed pursuant to BATS Rule 14.11(i), including generically listed Managed Fund Shares, are included within the definition of "security" or "securities" as those terms are used in the BATS Rules. *See* BATS Rule 14.11(i)(2). Accordingly, Managed Fund Shares are subject to the full set of rules and procedures that govern the trading of securities on the Exchange. *See* Amendment No. 6, *supra* note 14, at 42.

[50] *See* Amendment No. 6, *supra* note 14, at 27–28.

[51] 15 U.S.C. 78f(b)(5).

[52] *See, e.g.,* Securities Exchange Act Release No. 72666 (July 3, 2014), 79 FR 44224 (July 30, 2014) (SR–NYSEArca–2013–122).

[53] *See* Amendment No. 6, *supra* note 14, at 29.

[54] *See* BATS Rule 14.11(e)(10)(E)(ii)(a).

[55] *See* proposed BATS Rule 14.11(i)(3)(E).

[56] 15 U.S.C. 78f(b)(5).

[57] 15 U.S.C. 78s(b)(2).

100), as modified by Amendment No. 6 thereto, be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[58]

Brent J. Fields,

Secretary.

[FR Doc. 2016–17824 Filed 7–27–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78392; File No. SR–NASDAQ–2016–098]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing of Proposed Rule Change To Modify the Complimentary Services Offered to Certain New Listings

July 22, 2016.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 11, 2016, The Nasdaq Stock Market LLC ("Nasdaq" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify the complimentary services offered to certain new listings.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaq.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Nasdaq offers complimentary services to companies listing on the Nasdaq Global and Global Select Markets in connection with an initial public offering, upon emerging from bankruptcy, or in connection with a spin-off or carve-out from another company ("Eligible New Listings") and to companies that switch their listing from the New York Stock Exchange ("NYSE") to the Nasdaq Global or Global Select Markets ("Eligible Switches" and, together with Eligible New Listings, "Eligible Companies").[3] Nasdaq believes that this program offers valuable services to newly listing companies, designed to help ease the transition of becoming a public company or switching markets, makes listing on Nasdaq more attractive to these companies, and also provides Nasdaq Corporate Solutions[4] the opportunity to demonstrate the value of its services and forge a relationship with the company. Eligible Companies receive a whistleblower hotline, investor relations Web site, press release distribution services, interactive webcasting, and market analytic tools, and may receive a market surveillance service.[5] Based on Nasdaq's experience with the program and competitive changes,[6] Nasdaq proposes to modify its offering as described below.

First, Nasdaq currently offers Eligible Companies that have a market capitalization of $750 million or more a stock surveillance tool, through which an analyst attempts to determine who is buying and selling the company's stock. While any public company can use this offering, which is designed to enhance the company's investor relations activity, it may not be an appropriate fit for some companies, such as those that are closely held or otherwise have low liquidity or low volume. Other companies may prioritize different investor relations tools over stock surveillance. These companies therefore are more likely to derive value from a different market advisory service offered by Nasdaq Corporate Solutions. Accordingly, in order to make the package more attractive to these companies, Nasdaq proposes to allow companies eligible for this service to choose from the existing stock surveillance offering or, instead, to choose other alternatives, which are also designed to help companies identify current owners, potential buyers or sellers of their stock, or otherwise enhance their investor relations efforts. Specifically, instead of the existing offering, companies would be allowed to choose: (i) A global targeting package, where an investor targeting specialist will help focus the company's investor relations efforts on appropriate investors, tailor messaging to those investors' interests and measure the company's impact on their holdings; (ii) monthly ownership analytics and event driven targeting, which provide a monthly shareholder analysis and tracking report, which an analyst will help interpret during a monthly call, and a shareholder targeting plan around one event each year, such as a roadshow or investor conference;[7] or (iii) an annual perception study designed to identify how the company is perceived by key stakeholders and provide the company with actionable recommendations for enhancing its perception in the market. These alternative market advisory services are similar in that they all assist a company's investor relations efforts by providing information about current or potential investors to the company, but are designed to be valuable to companies based on their needs at differing times. The approximate retail value of the proposed new services ranges from $35,000 to $46,000 per year, as compared to the approximate retail value of $51,000 of the existing stock surveillance tool.[8]

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[58] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Exchange Act Release No. 65963 (December 15, 2011), 76 FR 79262 (December 21, 2011) (SR–NASDAQ–2011–122) (adopting IM–5900–7) (the "Original Filing"); Exchange Act Release No. 72669 (July 24, 2014), 79 FR 44234 (July 30, 2014) (SR–NASDAQ–2014–058) (adopting changes to IM–5900–7). These adopting releases are collectively referred to as the "Prior Filings."

[4] In November 2015, the name of NASDAQ OMX Corporate Solutions was changed to Nasdaq Corporate Solutions to reflect the rebranding of the holding company from NASDAQ OMX to Nasdaq, Inc. This change is reflected in the amended rule language.

[5] Only Eligible Companies with a market capitalization of $750 million or more receive the market surveillance service. This service is being renamed in this filing "stock surveillance" to better reflect its purpose.

[6] *See* Exchange Act Release No. 76127 (October 9, 2015), 80 FR 62584 (October 16, 2015) (SR–NYSE–2015–36) (modifying the services offered by NYSE to certain companies). *See also* Exchange Act Release No. 77401 (March 17, 2016), 81 FR 15585 (March 23, 2016) (SR–NYSEMKT–2016–12) (adopting a rule allowing NYSE MKT to offer certain newly listed companies services).

[7] To fully utilize this service, the company will also have to subscribe to, and separately pay for, certain third party information, such as position reports from the Depositary Trust Corporation.

Second, Nasdaq proposes to create a new tier of services for Eligible Companies with a market capitalization of $5 billion or more. As noted in the Prior Filings, Nasdaq believes that it is appropriate to offer different services based on a company's market capitalization given that larger companies generally will need more and different governance, communication and intelligence services.[9] The listing of these companies also attracts the most attention and therefore enhances Nasdaq's image as a listing venue to the benefit of Nasdaq and all other Nasdaq-listed companies. Based on Nasdaq's experience, Nasdaq has concluded that companies with a market capitalization of $5 billion or more have more complex investor relations functions and frequently have more shareholders and a greater change in their shareholdings, and therefore can benefit from, and are more likely to purchase at the end of the complimentary period, investor targeting or perception studies in addition to surveillance services. As such, Nasdaq proposes to offer these companies the choice of a second market advisory tool.[10]

Third, Nasdaq has determined to enhance the value of the package offered to Eligible Switches. NYSE recently modified the ongoing services it offers its listed companies, claiming to increase the value of those services.[11] As a result, while most companies pay substantially lower listing fees on Nasdaq, some companies considering whether to switch to Nasdaq nonetheless will need a greater incentive to forego the services offered by NYSE, which are now valued higher by NYSE. Accordingly, Nasdaq proposes to increase the number of users of the market analytic tool to three users for Eligible Switches with a market capitalization of $750 million or more but less than $5 billion and to four users for Eligible Switches with a market capitalization of $5 billion or more.[12] In addition, Nasdaq proposes to increase the term of the complimentary services from three to four years for any Eligible Switch with a market capitalization of $750 million or greater. This restores some features and the term of complimentary services that was previously in effect for such companies.[13]

The proposed rule change would also update the values and descriptions of the services offered as follows. The approximate retail value of the investor relations Web site would be updated from $15,000 to $16,000, the market analytic tool for two users from $30,000 to $29,000, and the stock surveillance tool from $50,000 to $51,000.[14] In addition, the proposed rule change will eliminate rounding in the total retail value of the services offered each category of Eligible Company. The description of the market analytic tool would be changed to reflect the addition of mobile access to the users of that service and to add the value of that offering for three and four users ($40,000 and $51,000, respectively). The "Interactive Webcasting" service would be renamed "Audio Webcasting" to reflect better the voice-only nature of the service, which is delivered through a platform branded with the company's name and logo that allows real-time questions from the audience. The four audio webcasts also would be described as a "package" to reflect better the basis for approximate retail value provided.[15] In addition, Nasdaq proposes to rename the current "Press Release" service to "Disclosure Services," to better reflect the availability of EDGAR and XBRL services, and to specify that these services are provided as an annual stipend usable with Nasdaq Corporate Solutions.[16] Nasdaq also proposes to delete the reference to factors affecting the number of press releases available because the revised rule would explicitly state that it is an annual stipend and would emphasize disclosure services generally rather than just press releases.

Where a company has a choice among different complimentary services under the revised rule, it must make its selection when it first begins to use a complimentary service. A company will not be permitted to subsequently change to a different complimentary service offered in the package. Of course the company can discontinue using a service at any time without penalty and can also elect to purchase from Nasdaq Corporate Solutions a service alternative that was previously declined or a comparable service from another competitor.

Nasdaq will implement this rule filing upon approval. Any company receiving services under the terms of the Prior Filings on the date of approval may elect to receive services under the revised terms in this proposed rule filing (even if those services were not available at the time the company listed on Nasdaq). If a company elects to receive services under the proposed rules, the services that the company is eligible to receive will be determined based on its status and market capitalization at the time of its original listing. The length of time that services are available to the company under the revised package will be calculated from the company's original listing date. In this manner, the rule will be applied prospectively, from approval.

Finally, the proposed rule change would modify the introductory note to IM–5900–7 to reference the historical changes to the program and explain the impact of the revisions to companies that are already listed. The rule would also be reorganized to enhance its readability and usability.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of section 6 of the Act,[17] in general, and sections 6(b)(4), 6(b)(5), and 6(b)(8), in particular, in that the proposal is designed, among other things, to provide for the equitable allocation of reasonable dues, fees, and other charges among Exchange members and issuers and other persons using its facilities and to promote just and equitable principles of trade, and is not designed to permit unfair discrimination between issuers, and in that the rules of the Exchange do not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. In the Prior Filings, the Commission determined that existing IM–5900–7 is consistent with these provisions of the Act.[18] Nothing proposed herein changes that conclusion. Nasdaq faces competition in the market for listing services,[19] and competes, in part, by offering valuable services to companies, including services that ease the companies' transition to being public or listed on a new exchange. Under the proposed changes, these services would be available for a small number of all public companies [20] and would remain available only for a short period of two to four years, as in the Original Filing.

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[8] Nasdaq also proposes to update the description of the stock surveillance tool to clarify that it is a single, dedicated analyst who provides that service, as opposed to the team approach used for the proposed alternative market advisory tools, and to note that the analyst attempts to identify institutional buyers and sellers in the company's stock.

[9] Exchange Act Release No. 65963, 76 FR at 79265.

[10] In describing the value of the services in the rule text, Nasdaq presumed that a company would use stock surveillance, which has an approximate retail value of $51,000, and global targeting, which has an approximate retail value of $40,000. A company using the stock surveillance tool would be unlikely also to use the monthly ownership analytics and event driven targeting because there is considerable overlap between these services. Companies could, of course, select different combinations of the four offered services that do not overlap, but these other combinations would have lower total approximate retail values.

[11] Exchange Act Release No. 76127, *supra*.

[12] This service has a retail value of approximately $29,000 per year for two users, $40,000 for three users, and $51,000 for four users.

[13] Prior to July 2014, Nasdaq offered market analytic tools for four users to all Eligible Companies. In addition, Nasdaq offered Eligible Switches (but not other companies) with a market capitalization of $500 million or more four years of complimentary services. The 2014 changes, as well as the changes proposed in this filing to restore some of those services, reflects the competition among exchanges for listings. Securities Exchange Act Release No. 72669, 79 FR at 44235.

[14] The Commission has previously held that such updates are required by the Act. Exchange Act Release No. 72669, 79 FR at 44236.

[15] Four separately purchased webcasts would cost more than four purchased together as a package. The approximate retail value provided is, and always has been, based on the purchase of such a package.

[16] These are changes to reflect the way the service has always been offered.

[17] 15 U.S.C. 78f.

Under the existing rule, Nasdaq offers companies with a market capitalization of $750 million or more a stock surveillance service and Nasdaq has justified why providing this service to such companies is not unfairly discriminatory in the Prior Filings. Nasdaq proposes to allow these companies to continue to receive this service or, at their election, to choose a different market advisory service with a lower retail value, but which may be more meaningful to the company. The addition of this flexibility does not change Nasdaq's fees nor how those fees are allocated among issuers and other persons using Nasdaq's facilities, and it does not unfairly discriminate against any issuer, because any issuer currently eligible to receive the higher value stock surveillance service would only receive a lower value service if the issuer voluntarily determines that the other service is more valuable to it based on its circumstances. Nasdaq believes that by allowing companies the ability to choose an appropriate market advisory tool, instead of offering just stock surveillance, the package will be more enticing. Therefore, this change will enhance competition among listing exchanges, rather than impose any burden on that competition. In addition, by providing companies the ability to choose a more meaningful market advisory tool, Nasdaq believes that these companies will have a better experience with the applicable tool; as a result, the companies are more likely to continue to use their chosen service. The ability to choose could create additional users of the service class and enhance competition among service providers.

Nasdaq also proposes to allow Eligible Companies with a market capitalization of $5 billion or more to receive an additional market advisory service. As noted above, Nasdaq has concluded that companies with a market capitalization of $5 billion or more have more complex investor relations functions and frequently have more shareholders and face greater changes in their shareholdings. These companies therefore can benefit from additional market advisory services and are more likely to purchase additional services at the end of the complimentary period. There is also enhanced competition for listing of these larger companies and offering them an additional market advisory service reflects that competition and the greater fees they generally pay. Nasdaq believes that this enhanced need, the increased likelihood that the company will purchase the service at the end of the complimentary period, the increased competition for these listings, and the greater fees generally paid by these companies form an equitable and reasonable basis to distinguish these issuers; as a result, Nasdaq does not believe that this change unfairly discriminates between issuers. Nasdaq also believes that by allowing certain companies the ability to choose an additional market advisory tool, the package will be more enticing and therefore will enhance competition among listing exchanges, rather than impose any burden on that competition. In addition, by providing companies the ability to use an additional market advisory tool, Nasdaq believes that these companies are more likely to continue to use their chosen service on an ongoing basis when the complimentary period is over. This ability to choose could create additional users of the service class and enhance competition among service providers.

Nasdaq previously offered market analytic tools for four users to all Eligible Companies but reduced that to two users based on Nasdaq's experience with company use of the service.[21] Upon further consideration, Nasdaq believes that allowing a third user of its market analytics tools to Eligible Switches with a market capitalization of $750 million or more and a fourth user for Eligible Switches with a market capitalization of $5 billion or more better addresses Nasdaq's prior experience and is appropriate and not unfairly discriminatory. Larger companies often have more complex investor relations functions and therefore can benefit from additional market analytic user seats. Offering these companies additional user seats based on their size and needs therefore enables Nasdaq to compete better for listings, which is a nondiscriminatory reason to distinguish among issuers. In addition, Nasdaq believes that it is appropriate to distinguish Eligible Switches from other Eligible New Listings because Eligible Switches generally have larger investor relations teams already in place and therefore can benefit from the additional user seats. On the other hand, many Eligible New Listings work with investment banks and other firms that provide ongoing support for a period after their listing while the company's investor relations programs mature, and these companies therefore have less need for the additional user seats. In addition, Eligible Switches forego services paid for by their former exchange and larger companies forego more services.[22] Therefore, Nasdaq believes that it is equitable and not unfairly discriminatory to offer these additional user seats only to Eligible Switches and not to Eligible New Listings and to base the number of additional seats on the Eligible Switches' size.

The proposed change to reinstate the four-year term of services provided to Eligible Switches with a market capitalization of $750 million or more restores the term of complimentary services that was in effect for these companies prior to the 2014 changes.[23] This change reflects Nasdaq's ongoing assessment of the competitive market for listings and does not place any unnecessary burden on that competition.

The adjustments proposed to reflect changes in the fair market values of the services offered do not meaningfully affect the allocation of Nasdaq's fees and therefore also do not impact the Commission's prior conclusions. These changes, in fact, were found to be necessary by the Commission in the Prior Filings.[24] Similarly, the changes to rename certain services to better reflect the service offered, refer to Nasdaq Corporate Solutions and reorganize the rule are clarifying changes, which have no impact on fees and how they are allocated or on competition.

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[18] Exchange Act Release No. 65963, 76 FR at 79267; Exchange Act Release No. 72669, 79 FR at 44234.

[19] The Justice Department has noted the intense competitive environment for exchange listings. *See* "NASDAQ OMX Group Inc. and IntercontinentalExchange Inc. Abandon Their Proposed Acquisition Of NYSE Euronext After Justice Department Threatens Lawsuit" (May 16, 2011), available at *http://www.justice.gov/atr/public/press_releases/2011/271214.htm.*

[20] For example, in 2014 there were 309 total IPOs in the U.S. and Nasdaq listed 189 of them; 147 qualified for services under IM–5900–7. In 2015, there were 196 total IPOs in the U.S. and Nasdaq listed 143 of them; 98 qualified for services under IM–5900–7. Two exchange switches qualified for services under IM–5900–7 in 2014 and five qualified in 2015. In contrast, according to FactSet, there are approximately 13,000 public companies in the U.S. on June 29, 2016, including more than 5,000 listed on exchanges.

[21] Securities Exchange Act Release No. 72669, *supra.*

[22] While NYSE bases its service tiers for currently listed companies on shares outstanding, as described in the Prior Filings, Nasdaq believes that companies with higher market capitalizations also generally will have more shares outstanding.

[23] Exchange Act Release No. 65963, 76 FR 79262.

Nasdaq believes that it is not unfairly discriminatory to offer the revised service package only to currently listed companies that are receiving services at the time of the proposal's approval, and not to other currently listed companies. Companies receiving complimentary services are still in the process of sampling Nasdaq Corporate Solutions' offering and both the companies and Nasdaq Corporate Solutions will benefit from the ability of the company to utilize the revised services. Moreover, because Nasdaq Corporate Solutions continues to provide the complimentary services to these companies, extending their term and providing additional seats and advisory services is a seamless process. On the other hand, companies that are not currently receiving complimentary services from Nasdaq Corporate Solutions will have either entered into binding contractual agreements with Nasdaq Corporate Solutions and other providers for the specific services they require or determined that they do not wish to purchase the services. Extending the benefits of the revised rule to such companies would cause them to have duplicative services to what they have already contracted or provide them with the option for a service that they have already concluded they do not want. Accordingly, providing the benefit of the changes only to those companies receiving services when the proposed rule change is approved is not unfairly discriminatory.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. As described in the statutory basis section, above, the proposed rule change responds to competitive pressures in the market for listings. Nasdaq believes the proposed changes will result in a more enticing package for potential listings and therefore will enhance competition among listing exchanges. The proposed changes to allow companies the ability to choose a more meaningful market advisory tool will provide companies a better experience with these tools, the proposed change to allow certain companies to receive two market advisory tools will expose eligible companies to additional service options. As a result, Nasdaq believes that when the complimentary period ends these companies are more likely to continue to use the Nasdaq Corporate Solutions service or a competing service, whereas otherwise they may not be exposed to the value of these services and therefore may not purchase any. This will create additional users of the service class and enhance competition among service providers. In addition, other service providers can also offer similar services to companies, thereby increasing competition to the benefit of those companies and their shareholders. Accordingly, Nasdaq does not believe the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NASDAQ–2016–098 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2016–098. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2016–098 and should be submitted on or before August 18, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

Brent J. Fields,

Secretary.

[FR Doc. 2016–17822 Filed 7–27–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736.

Extension:

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[24] Exchange Act Release No. 72669, 79 FR at 44236.

[25] 17 CFR 200.30–3(a)(12).

Rule 15Ba2–5, SEC File No. 270–91, OMB Control No. 3235–0088.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (“PRA”) (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (“Commission”) has submitted to the Office of Management and Budget (“OMB”) a request for approval of extension of the existing collection of information provided for in Rule 15Ba2–5 (17 CFR 240.15Ba2–5), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (“Exchange Act”).

On July 7, 1976, effective July 16, 1976 (*see* 41 FR 28948, July 14, 1976), the Commission adopted Rule 15Ba2–5 under the Exchange Act to permit a duly-appointed fiduciary to assume immediate responsibility for the operation of a municipal securities dealer’s business. Without the rule, the fiduciary would not be able to assume operation until it registered as a municipal securities dealer. Under the rule, the registration of a municipal securities dealer is deemed to be the registration of any executor, administrator, guardian, conservator, assignee for the benefit of creditors, receiver, trustee in insolvency or bankruptcy, or other fiduciary, appointed or qualified by order, judgment, or decree of a court of competent jurisdiction to continue the business of such municipal securities dealer, provided that such fiduciary files with the Commission, within 30 days after entering upon the performance of his duties, a statement setting forth as to such fiduciary substantially the same information required by Form MSD or Form BD. The statement is necessary to ensure that the Commission and the public have adequate information about the fiduciary.

There is approximately 1 respondent per year that requires an aggregate total of 4 hours to comply with this rule. This respondent makes an estimated 1 annual response. Each response takes approximately 4 hours to complete. Thus, the total compliance burden per year is 4 burden hours. The approximate cost per hour is $20, resulting in a total internal cost of compliance for the respondent of approximately $80 (*i.e.*, 4 hours × $20).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following Web site: *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: July 22, 2016.

Brent J. Fields,

Secretary.

[FR Doc. 2016–17820 Filed 7–27–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78394; File No. SR–Phlx–2016–77]

Self-Regulatory Organizations; NASDAQ PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Price Improvement XL Pricing

July 22, 2016.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that, on July 14, 2016, NASDAQ PHLX LLC (“Phlx” or “Exchange”) filed with the Securities and Exchange Commission (“SEC” or “Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange’s Pricing Schedule at section IV, part A, to amend Price Improvement XL (“PIXL”) Pricing.[3]

While changes to the Pricing Schedule pursuant to this proposal are effective upon filing, the Exchange has designated these changes to be operative on August 1, 2016.

The text of the proposed rule change is available on the Exchange’s Web site at *http://nasdaqphlx.cchwallstreet.com/*, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend PIXL Pricing in section IV, part A, to reduce the Penny Pilot Options Specialist[4] or Market Maker[5] Responder fee from $0.30 to

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] PIXL℠ is the Exchange’s price improvement mechanism known as Price Improvement XL or PIXL. A member may electronically submit for execution an order it represents as agent on behalf of a public customer, broker-dealer, or any other entity (“PIXL Order”) against principal interest or against any other order (except as provided in Rule 1080(n)(i)(F) it represents as agent (“Initiating Order”), provided it submits the PIXL order for electronic execution into the PIXL Auction pursuant to Rule 1080. *See* Exchange Rule 1080(n).

[4] The term “Specialist” shall apply to the account of a Specialist (as defined in Exchange Rule 1020(a)). A Specialist is an Exchange member who is registered as an options specialist pursuant to Rule 501(a). An options Specialist includes a Remote Specialist which is defined as an options specialist in one or more classes that does not have a physical presence on an Exchange floor and is approved by the Exchange pursuant to Rule 501.

[5] The term “Market Maker” will be utilized to describe fees and rebates applicable to Registered Options Traders (“ROTs”), Streaming Quote Traders (“SQTs”), Remote Streaming Quote Traders (“RSQTs”). An ROT is defined in Exchange Rule 1014(b) is a regular member or a foreign currency options participant of the Exchange located on the trading floor who has received permission from the Exchange to trade in options for his own account. A ROT includes SQTs and RSQTs as well as on and off-floor ROTS. An SQT is defined in Exchange Rule 1014(b)(ii)(A) as an ROT who has received permission from the Exchange to generate and submit option quotations electronically in options to which such SQT is assigned. An RSQT is defined in Exchange Rule in 1014(b)(ii)(B) as an ROT that is a member affiliated with an RSQTO with no physical trading floor presence who has received permission from the Exchange to generate and submit option quotations electronically in options to which such RSQT has been assigned. A Remote Streaming Quote Trader Organization or “RSQTO,” which may also be referred to as a Remote Market Making Organization (“RMO”), is a member organization in good standing that satisfies the

Continued

$0.25 per contract. The Exchange believes that this reduction will further align pricing, taking into consideration the Marketing Fee. Additional detail on this rule change is provided below.

Amendment to Section IV, Part A—PIXL Pricing

PIXL pricing is located in section IV, part A, of the Exchange's Pricing Schedule. A PIXL Auction Initiating Order is assessed $0.07 per contract. There are various incentives to lower the Initiating Order fee to $0.05 or $0.00.[6] With respect to PIXL order executions in Multiply-Listed Options (including ETFs, ETNs, and indexes which are Multiply Listed), when the PIXL Order is contra to the Initiating Order a Customer PIXL Order will be assessed $0.00 per contract and Non-Customer PIXL Orders will be assessed $0.30 per contract. When a PIXL Order is contra to a PIXL Auction Responder,[7] a Customer PIXL Order will be assessed $0.00 per contract, other Non-Customer PIXL Orders will be assessed $0.30 per contract in Penny Pilot Options or $0.38 per contract in Non-Penny Pilot Options. A Responder that is a Specialist or a Market Maker will be assessed $0.30 per contract in Penny Pilot Options or $0.40 per contract in Non-Penny Pilot Options. Other Non-Customer Responders will be assessed $0.48 per contract in Penny Pilot Options or $0.70 per contract in Non-Penny Pilot Options when contra to a PIXL Order. A Responder that is a Customer will be assessed $0.00 per contract in Penny Pilot Options and Non-Penny Pilot Options.[8] All other fees discussed in Section II, including Marketing Fees[9] and surcharges, will also apply as appropriate. Today, a Responder that is a Specialist or Market Maker would be assessed $0.30 per contract in Penny Pilot Options plus an additional $0.25 per contract Marketing Fee on that transaction for a total fee of $0.55 per contract.

The Exchange proposes to lower the Responder Fee for a Specialist or Market Maker from $0.30 to $0.25 per contract in Penny Pilot Options. The total Responder Fee for a Specialist or Market Maker in Penny Pilot Options would therefore be $0.25 per contract (Responder Fee) plus $0.25 per contract (Marketing Fee) for a total of $0.50 per contract. The Exchange believes that this fee reduction would better align Specialists and Market Makers responding in a PIXL auction with other responders, in Penny Pilot Options, who are not subject to the Marketing Fee.

2. Statutory Basis

The Exchange believes that its proposal is consistent with section 6(b) of the Act,[10] in general, and furthers the objectives of sections 6(b)(4) and 6(b)(5) of the Act,[11] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system "has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies."[12]

Likewise, in *NetCoalition* v. *Securities and Exchange Commission*[13] ("NetCoalition") the D.C. Circuit upheld the Commission's use of a market-based approach in evaluating the fairness of market data fees against a challenge claiming that Congress mandated a cost-based approach.[14] As the court emphasized, the Commission "intended in Regulation NMS that 'market forces, rather than regulatory requirements' play a role in determining the market data . . . to be made available to investors and at what cost."[15]

Further, "[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . ."[16] Although the court and the SEC were discussing the cash equities markets, the Exchange believes that these views apply with equal force to the options markets.

Amendment to Section IV, Part A—PIXL Pricing

The Exchange's proposal to amend section IV, part A to lower the PIXL Responder Fee for a Specialist or Market Maker from $0.30 to $0.25 per contract in Penny Pilot Options is reasonable because Specialists and Market Makers are subject to the Marketing Fee, whereas other types of market participants are not assessed the Marketing Fee. By lowering the PIXL Responder Fee for a Specialist or Market Maker from $0.30 to $0.25 per contract these market participants would be more closely aligned with other responders. The Exchange believes that Specialists and Market Makers will be

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RSQTO readiness requirements in Rule 507(a). RSQTs may also be referred to as Remote Market Markers ("RMMs").

[6] If the member or member organization qualifies for the Tier 4 or 5 Customer Rebate in Section B the member or member organization will be assessed $0.05 per contract. If the member or member organization executes equal to or greater than 3.00% of National Customer Volume in Multiply-Listed equity and ETF Options Classes (excluding SPY Options) in a given month, the member or member organization will be assessed $0.00 per contract for Complex PIXL Orders. Any member or member organization under Common Ownership with another member or member organization that qualifies for a Customer Rebate Tier 4 or 5 in Section B, or executes equal to or greater than 3.00% of National Customer Volume in Multiply-Listed equity and ETF Options Classes (excluding SPY Options) in a given month will receive one of the PIXL Initiating Order discounts as described above. The Initiating Order Fee for Professional, Firm, Broker-Dealer, Specialist and Market Maker orders that are contra to a Customer PIXL Order will be reduced to $0.00 if the Customer PIXL Order is greater than 399 contracts. See Chapter IV, Part A.

[7] A PIXL Auction Responder or a resting order or quote that was on the Phlx book prior to the auction are all Non-Initiating Order interest.

[8] When a PIXL Order is contra to a resting order or quote a Customer PIXL Order will be assessed $0.00 per contract, other Non-Customer will be assessed $0.30 per contract and the resting order or quote will be assessed the appropriate Options Transaction Charge in Section II.

[9] The Exchange assesses a Marketing Fee of $0.25 per contract for options that are trading in the Penny Pilot Program and $0.70 per contract for remaining equity options on trades resulting from either Directed or non-Directed Orders that are delivered electronically and executed on the Exchange, the above fees will be assessed on Specialists, Market Makers and Directed ROTs on those trades when the Specialist unit or Directed ROT elects to participate in the Marketing program. No Marketing Fees are assessed on trades not delivered electronically. No Marketing Fees are assessed in Professional Orders. *See* Section II of the Pricing Schedule. The term "Directed Order" means any order (other than a stop or stop-limit order as defined in Rule 1066) to buy or sell which has been directed to a particular specialist, RSQT, or SQT by an Order Flow Provider, as defined in Rule 1080(l).

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(4) and (5).

[12] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) ("Regulation NMS Adopting Release").

[13] *NetCoalition* v. *SEC,* 615 F.3d 525 (D.C. Cir. 2010).

[14] *See NetCoalition,* at 534–535.

[15] *Id.* at 537.

[16] *Id.* at 539 (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

encouraged to respond to PIXL auctions with the lower fee. The proposed Non-Customer fees are lower than fees assessed to Non-Customers by other options exchanges.[17]

The Exchange's proposal to amend section IV, part A to lower the PIXL Responder Fee for a Specialist or Market Maker from $0.30 to $0.25 per contract in Penny Pilot Options is equitable and not unfairly discriminatory for the following reasons. The differential as between Specialists and Market Makers and other Non-Customers (Professionals,[18] Firms[19] and Broker-Dealers[20]) is not misaligned because Specialists and Market Makers pay a Marketing Fee.[21] This proposal decreases the differential as between the Initiating Order Fee ($0.07 presuming no discount) and the Specialist or Market Maker contra party to the PIXL Order (proposed $0.25 per contract) for Penny Pilot Options. Specialists and Market Makers would receive lower prices because they have obligations to the market and regulatory requirements, which normally do not apply to other market participants in the continuous market, and as such the Exchange continues to believe Specialists and Market Makers should receive certain discounts in auctions.[22] Additionally, the Marketing Fee is only paid by Specialists and Market Makers. Other Non-Customer Responders (Firms, Professionals and Broker-Dealers) are assessed $0.48 per contract in Penny Pilot Options. All non-Customer market participants that do not engage in market making (Firms, Professionals and Broker-Dealers) are treated in a uniform manner. Customers will continue to be assessed no fee, as is the case today because Customer liquidity benefits all market participants by providing more trading opportunities, which attracts market makers. An increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. In terms of inter-market competition, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

In this instance, the proposed changes to the charges assessed and credits available to member firms for execution of securities in securities of all three Tapes do not impose a burden on competition because the Exchange's execution services are completely voluntary and subject to extensive competition both from other exchanges and from off-exchange venues. The proposed PIXL Responder fees do not impose an undue burden on inter-market competition for the reasons described herein. In sum, if the changes proposed herein are unattractive to market participants, it is likely that the Exchange will lose market share as a result. Accordingly, the Exchange does not believe that the proposed changes will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

The Exchange's proposal to amend section IV, part A to lower the PIXL Responder Fee for a Specialist or Market Maker from $0.30 to $0.25 per contract in Penny Pilot Options does not impose an undue burden on intra-market competition because the differential between the Initiating Order Fee and the Specialist or Market Maker contra party to the PIXL Order ($0.07 (presuming no discount) vs. $0.25 per contract for Penny Pilot Options is being decreased. The Marketing Fee is only paid by Specialists and Market Makers and not other market participants. Specialists and Market Makers would receive lower prices because have obligations to the market and regulatory requirements, which normally do not apply to other market participants in the continuous market, and as such the Exchange continues to believe Specialists and Market Makers should receive certain discounts in auctions.[23] Other Non-Customer Responders (Firms, Professionals and Broker-Dealers) are assessed $0.48 per contract in Penny Pilot Options. All non-Customer market participants that do not engage in market making (Firms, Professionals and Broker-Dealers) are treated in a uniform manner. Customers will continue to be assessed no fee, as is the case today because liquidity benefits all market participants by providing more trading opportunities, which attracts market makers. An increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3)(A)(ii) of the Act.[24]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

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[17] *See* NYSE MKT Inc. ("NYSE Amex") Fees and Charges. Specifically, the RFR Response Penny Pilot Option Fee (Non-Customer) is $0.50 per contract for the CUBE auction. CUBE is NYSE Amex's electronic price improvement auction for options. This mechanism is similar to the PIXL auction. MIAX assesses a Responder to the Prime Auction a per contract Penny Pilot fee of $0.50 per contract to all market participants (including priority customer). PRIME is MIAX's electronic price improvement auction for options. This mechanism is similar to the PIXL auction.

[18] The term "Professional" applies to transactions for the accounts of Professionals, as defined in Exchange Rule 1000(b)(14) means any person or entity that (i) is not a broker or dealer in securities, and (ii) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s).

[19] The term "Firm" applies to any transaction that is identified by a member or member organization for clearing in the Firm range at The Options Clearing Corporation.

[20] The term "Broker-Dealer" applies to any transaction which is not subject to any of the other transaction fees applicable within a particular category.

[21] *See* note 9 above.

[22] *See* Rule 1014 titled "Obligations and Restrictions Applicable to Specialists and Registered Options Traders."

[23] *Id.*

[24] 15 U.S.C. 78s(b)(3)(A)(ii).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2016–77 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2016–77. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2016–77, and should be submitted on or before August 18, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

Brent J. Fields,

Secretary.

[FR Doc. 2016–17823 Filed 7–27–16; 8:45 am]

BILLING CODE 8011–01–P

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[25] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

In the Matter of American Transportation Holdings, Inc.; Order of Suspension of Trading

July 26, 2016.

It appears to the Securities and Exchange Commission that the public interest and the protection of investors require a suspension of trading in the securities of American Transportation Holdings, Inc. (CIK No. 0001404526) because of recent, unusual and unexplained market activity in the company's stock taking place during a suspicious promotional campaign, and because of concerns about the accuracy of publicly available information, including but not limited to company press releases issued in June and July 2016. American Transportation Holdings Inc. is a Nevada corporation with its principal executive offices in Littleton, Colorado, with stock quoted on OTC Link (previously "Pink Sheets") operated by OTC Markets Group, Inc. under the ticker symbol ATHI.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed company is suspended for the period from 9:30 a.m. EDT on July 26, 2016, through 11:59 p.m. EDT on August 8, 2016.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2016–17965 Filed 7–26–16; 4:15 pm]

BILLING CODE 8011–01–P

DEPARTMENT OF STATE

[Delegation of Authority No. 398]

Authority To Submit Declarations and Claim Privileges on Behalf of the United States Under Military Rules of Evidence 505 and 506

By virtue of the authority vested in the Secretary of State, including the Department of State Basic Authorities Act, as amended (22 U.S.C. 2651a), I hereby delegate to the Legal Adviser, to the extent authorized by law, the authority to claim the privileges and provide the declarations described in Military Rules of Evidence 505 and 506.

Any act, executive order, regulation, or procedure subject to, or affected by, this delegation shall be deemed to be such act, executive order, regulation, or procedure as amended from time to time. This delegation of authority does not revoke or otherwise affect any other delegation of authority.

Notwithstanding this delegation of authority, this authority may be exercised by the Secretary, the Deputy Secretary, and the Deputy Secretary for Management and Resources.

This delegation of authority shall be published in the **Federal Register**.

Dated: July 20, 2016.

John F. Kerry,

Secretary of State.

[FR Doc. 2016–17936 Filed 7–27–16; 8:45 am]

BILLING CODE 4710–08–P

SURFACE TRANSPORTATION BOARD

[Docket No. MCF 21070]

SunTx Capital III Management Corp., et al.—Control—TBL Group, Inc.; GBJ, Inc.; Echo Tours and Charters L.P.

AGENCY: Surface Transportation Board.

ACTION: Notice tentatively approving and authorizing finance transaction.

SUMMARY: On June 28, 2016, SunTx Capital III Management Corp. (SunTx III), SunTx Capital Partners III GP, LP (SunTx GP), SunTx TBL Logistics Management Holdings, LP (SunTx Holdings), and TBL Logistics Management, LLC (TBL Logistics), along with TBL Group, Inc. (TBL Group) and the motor carriers of passengers it controls, GBJ, Inc. (GBJ) and Echo Tours and Charters L.P. (Echo) (collectively, Applicants) filed an application under 49 U.S.C. 14303 to acquire control of TBL Group, GBJ, and Echo. Concurrently with their application, the parties also filed a request for interim approval under 49 U.S.C. 14303(i). In a decision served on July 28, 2016 in related Docket No. MCF 21070 TA, interim approval was granted, effective on the service date of that decision. The Board is tentatively approving and authorizing the transaction, and if no opposing comments are timely filed, this notice will be the final Board action. Persons wishing to oppose the application must follow the rules at 49 CFR 1182.5 and 1182.8.

DATES: Comments must be filed by September 12, 2016. Applicants may file a reply by September 26, 2016. If no comments are filed by September 12, 2016, this notice shall be effective on September 13, 2016.

ADDRESSES: Send an original and 10 copies of any comments referring to Docket No. MCF 21070 to: Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, send one copy of comments to Applicants' representatives: Richard P. Schweitzer, Richard P. Schweitzer, P.L.L.C., 1717 K Street NW., Suite 900, Washington, DC 20006 (attorney for TBL Group, GBJ, and Echo) and Thomas J. Litwiler, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 920, Chicago, IL 60606–2832 (attorney for SunTx III, SunTx GP, SunTx Holdings, and TBL Logistics).

FOR FURTHER INFORMATION CONTACT: Allison Davis (202) 245–0378. Federal Information Relay Service (FIRS) for the hearing impaired: 1–800–877–8339.

SUPPLEMENTARY INFORMATION: Applicants assert the following facts. SunTx III, a noncarrier Texas corporation, is a general partner of SunTx GP, a noncarrier Texas limited partnership, which is, in turn, the general partner of SunTx Holdings, also a noncarrier Texas limited partnership. SunTx III, SunTx GP, and SunTx Holdings are components of SunTx Capital Partners, a private equity firm that invests in middle market manufacturing, distribution, and service companies. TBL Logistics is a newly formed noncarrier Delaware holding company. TBL Group is a noncarrier Texas corporation that owns and controls two federally regulated motor carriers of passengers: Echo d/b/a Echo Transportation (MC–755212) and GBJ d/b/a AFC Transportation (MC–369531).[1] Echo and GBJ, both incorporated in Texas, each own equal shares of TBL Group stock. TBL Group holds 100% of the stock of Echo and GBJ. Echo has been operating since 2011 and provides interstate charter, tour, limousine, school bus, and local city shuttle transportation in the Dallas, Fort Worth, Tyler, San Angelo, and Waco markets. GBJ has been operating for 24 years and provides interstate charter transportation, local city shuttle service, and sedan service in the Houston metropolitan area. GBJ operates motorcoaches, minibuses, transit buses, sedans, and limousines.

Applicants seek Board authority for control of TBL Group, Echo, and GBJ through the creation of TBL Logistics. Specifically, Applicants state that, as a result of this transaction, TBL Logistics would own TBL Group through which TBL Logistics would control Echo and GBJ. TBL Logistics would be owned 80.1% by SunTx Holdings and 19.9% by TBL Group.

Applicants assert that, as a result of the proposed transaction, Echo and GBJ would benefit from financing that would enable them to purchase additional vehicles to upgrade the combined fleet. Applicants state that vehicles that average more than 12 years of age would be replaced with newer, safer, and more reliable vehicles that would offer better utilization factors, higher fuel economy, and lower emissions, and would provide the public with safer, more cost effective and environmentally responsible transportation. Applicants further state that the infusion of capital would allow Echo and GBJ to expand their service offerings in their existing markets and explore the possibility of offering service in new markets as well.

Under 49 U.S.C. 14303(b), the Board must approve and authorize a transaction that it finds consistent with the public interest, taking into consideration at least: (1) The effect of the proposed transaction on the adequacy of transportation to the public; (2) the total fixed charges that result from the proposed transaction; and (3) the interest of affected carrier employees affected by the proposed transaction. Applicants submitted information, as required by 49 CFR 1182.2, including information to demonstrate that the proposed transaction is consistent with the public interest under 49 U.S.C. 14303(b), and a statement that the aggregate gross operating revenues of Echo and GBJ exceeded $2 million for the preceding 12-month period under 49 U.S.C. 14303(g).[2]

With respect to adequacy of transportation to the public, Applicants submit that the proposed transaction would not result in significant changes to the operations of Echo and GBJ. Applicants state that the proposed transaction would allow the companies to take advantage of better financial terms, which would allow them to replace aging vehicles on favorable terms. Applicants anticipate more efficient and effective service in each of the markets and that the transaction would enable Echo and GBJ to leverage the new investment to provide the same or greater level of transportation to the public. With respect to fixed charges, Applicants assert that the capital investment will lower interest payments on existing debt and allow them to secure attractive terms for additional financing of equipment acquisitions. Applicants also state that the proposed transaction would not have an overall negative impact on employees because, over time, the carriers would be able to grow by taking advantage of economies of scale, better financial terms, and increased buying power, which would result in increased service and additional personnel.

Applicants further claim that the proposed transaction would not have a material adverse effect on competition because Echo and GBJ do not plan on significantly altering their current operations, but would be taking advantage of efficiencies gained through improved capital financing. Applicants states that the areas served by Echo and GBJ have robust carrier competition. Specifically, in North Texas, Echo controls less than 10% of the charter, tour, shuttle, livery school, metro, and scheduled ground transportation market. Similarly, in South Texas, GBJ controls less than 10% of the charter, tour, shuttle, livery school, metro, and scheduled ground transportation market. Applicants note that areas served by the two motor carriers are largely separate and distinct, with a small amount of overlap in the larger markets. Applicants assert that the benefits associated with the transaction would only support increased competition. Applicants further reiterate the Board's findings in other cases regarding low barriers to entry into the interstate bus industry.

The Board finds that the proposed acquisition described in the application is consistent with the public interest and should be tentatively approved and authorized. If any opposing comments are timely filed, these findings will be deemed vacated, and, unless a final decision can be made on the record as developed, a procedural schedule will be adopted to reconsider the application. *See* 49 CFR 1182.6(c). If no opposing comments are filed by the expiration of the comment period, this notice will take effect automatically and will be the final Board action. Board decisions and notices are available on our Web site at *WWW.STB.DOT.GOV.*

This action is categorically excluded from environmental review under 49 CFR 1105.6(c).

It is ordered:

1. The proposed transaction is approved and authorized, subject to the filing of opposing comments.

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[1] In 2014, the Board authorized Texas Bus and Limo Acquisition Corp. (now known as TBL Group) to acquire control of five motor carriers of passengers. *Tex. Bus & Limo Acquis. Corp.—Control—GBJ, Inc.*, MCF 21058 (STB served July 9, 2014). Applicants state that, ultimately, only the acquisitions of GBJ and Echo were consummated.

[2] Applicants with gross operating revenues exceeding $2 million are required to meet the requirements of 49 CFR 1182.

2. If opposing comments are timely filed, the findings made in this notice will be deemed vacated.

3. This notice will be effective September 13, 2016, unless opposing comments are filed by September 12, 2016.

4. A copy of this notice will be served on: (1) The U.S. Department of Transportation, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590; (2) the U.S. Department of Justice, Antitrust Division, 10th Street & Pennsylvania Avenue NW., Washington, DC 20530; and (3) the U.S. Department of Transportation, Office of the General Counsel, 1200 New Jersey Avenue SE., Washington, DC 20590.

Decided: July 25, 2016.

By the Board, Chairman Elliott, Vice Chairman Miller, and Commissioner Begeman.

Brendetta S. Jones,

Clearance Clerk.

[FR Doc. 2016–17887 Filed 7–27–16; 8:45 am]

BILLING CODE 4915–01–P

TENNESSEE VALLEY AUTHORITY

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Tennessee Valley Authority.

ACTION: 30-Day notice of submission of information collection approval and request for comments.

SUMMARY: This is a renewal request for approval of the Application for Section 26a Permit (OMB No. 3316–0060). The information collection described below will be submitted to the Office of Management and Budget (OMB) at, *oira_submission@omb.eop.gov,* for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35, as amended). The Tennessee Valley Authority is soliciting public comments on this proposed collection as provided by 5 CFR 1320.8(d)(1).

DATES: Comments should be sent to the Agency Clearance Officer and the OMB Office of Information & Regulatory Affairs, Attention: Desk Officer for Tennessee Valley Authority, Washington, DC 20503, or email: *oira_submission@omb.eop.gov,* no later than August 29, 2016.

ADDRESSES: Requests for information, including copies of the information collection proposed and supporting documentation, should be directed to the Senior Privacy Program Manager: Christopher A. Marsalis, Tennessee Valley Authority, 400 W. Summit Hill Dr. (WT 5D), Knoxville, Tennessee 37902–1401; telephone (865) 632–2467 or email: *camarsalis@tva.gov;* or to Joy L. Lloyd, Tennessee Valley Authority, 400 W. Summit Hill Dr. (WT 5A), Knoxville, Tennessee 37902–1401; telephone (865) 632–8370 or email: *jllloyd@tva.gov;* or to the Agency Clearance Officer: Philip D. Propes, Tennessee Valley Authority, 1101 Market Street (MP 2C), Chattanooga, Tennessee 37402–2801; telephone (423) 751–8593 or email: *pdpropes@tva.gov.*

SUPPLEMENTARY INFORMATION:

Type of Request: Reauthorization.

Title of Information Collection: Section 26a Permit Application.

Frequency of Use: On occasion.

Type of Affected Public: Individuals or households, state or local governments, farms, businesses, or other for-profit, Federal agencies or employees, non-profit institutions, small businesses or organizations.

Small Businesses or Organizations Affected: Yes.

Federal Budget Functional Category Code: 452.

Estimated Number of Annual Responses: 1,800.

Estimated Total Annual Burden Hours: 3,600.

Estimated Average Burden Hours per Response: 2.0.

Need For and Use of Information: TVA Land Management activities and section 26a of the Tennessee Valley Authority Act of 1933, as amended, require TVA to collect information relevant to projects that will impact TVA land and land rights and review and approve plans for the construction, operation, and maintenance of any dam, appurtenant works, or other obstruction affecting navigation, flood control, or public lands or reservations across, along, or in the Tennessee River or any of its tributaries. The information is collected via paper forms and/or electronic submissions and is used to assess the impact of the proposed project on TVA land or land rights and statutory TVA programs to determine if the project can be approved. Rules for implementation of TVA's section 26a responsibilities are published in 18 CFR part 1304.

Philip D. Propes,

Director, Enterprise Information Security and Policy.

[FR Doc. 2016–17819 Filed 7–27–16; 8:45 am]

BILLING CODE 8120–08–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Eleventh Meeting Special Committee 231 TAWS

AGENCY: Federal Aviation Administration (FAA), U.S. Department of Transportation (DOT).

ACTION: Eleventh Meeting Special Committee 231 TAWS.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of Eleventh Meeting Special Committee 231 TAWS.

DATES: The meeting will be held September 20–23, 2016, 9:00 a.m. to 5:00 p.m. Tuesday, Wednesday, Thursday, 9:00 a.m. to 1:00 p.m. Friday.

ADDRESSES: The meeting will be held at: RTCA, Inc., 1150 18th Street NW., Suite 910, Washington, DC 20036. Individuals wishing for WebEx/Audio information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Rebecca Morrison at *rmorrison@rtca.org* or (202) 330–0654 or The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of the Eleventh Meeting Special Committee 231 TAWS. The agenda will include the following:

Tuesday, September 20, 2016—9:00 a.m.–5:00 p.m.

(1) Welcome/Introduction
(2) Administrative Remarks
(3) Agenda Review
(4) Summary of Pre-FRAC comments received on Strawman
(5) Other Business
(6) Date and Place of Next Meeting

Wednesday, Thursday, September 21st, 22nd—9:00 a.m.–5:00 p.m.

Continuation of Plenary or Working Group Session

Friday, September 23rd—9:00 a.m.–1:00 p.m.

Continuation of Plenary or Working Group Session

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on July 25, 2016.

Mohannad Dawoud,

Management & Program Analyst, Partnership Contracts Branch, ANG–A17, NextGen, Procurement Services Division, Federal Aviation Administration.

[FR Doc. 2016–17935 Filed 7–27–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

July 25, 2016.

The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

DATES: Comments should be received on or before August 29, 2016 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimates, or any other aspect of the information collections, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8117, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained by emailing *PRA@treasury.gov,* calling (202) 622–1295, or viewing the entire information collection request at *www.reginfo.gov.*

Alcohol and Tobacco Tax and Trade Bureau (TTB)

OMB Control Number: 1513–0016.

Type of Review: Revision of a currently approved collection.

Title: Drawback on Wines Exported.

Form: TTB F 5120.24.

Abstract: The Internal Revenue Code (IRC) at 26 U.S.C. 5062(b), provides, in general, that exporters of taxpaid domestic wine may claim "drawback" of the Federal excise tax paid or determined on the exported wine. Exporters use TTB F 5120.24 to document the wine's exportation and to submit drawback claims for the exported wine. TTB uses the provided information to determine if the exported wine is eligible for drawback and to calculate the amount of drawback due. This information is necessary to protect the revenue.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 179.

OMB Control Number: 1513–0031.

Type of Review: Revision of a currently approved collection.

Title: Specific and Continuing Transportation Bond—Distilled Spirits or Wines Withdrawn for Transportation to Manufacturing Bonded Warehouse—Class Six.

Form: TTB F 5100.12, TTB F 5110.67.

Abstract: The IRC at 26 U.S.C. 5214(a)(6) and 5362(c)(4) authorizes the transfer without payment of tax of, respectively, distilled spirits and wine from a bonded premises to certain customs bonded warehouses. Under 19 U.S.C. 1311, bonds are required for such transfers to protect the revenue. In order to provide proprietors of manufacturing bonded warehouses with operational flexibility based on individual need, TTB allows the filing of either a specific bond to cover a single shipment, using form TTB F 5100.12, or a continuing bond to cover multiple shipments, using form TTB F 5110.67.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 50.

OMB Control Number: 1513–0061.

Type of Review: Extension of a currently approved collection.

Title: Letterhead Applications and Notices Relating to Denatured Spirits (TTB REC 5150/2).

Abstract: Under the IRC at 26 U.S.C. 5214, denatured spirits (alcohol to which denaturants have been added to render it unfit for beverage purposes) may be withdrawn from distilled spirits plants free of tax for nonbeverage industrial purposes in the manufacture of personal and household products. Since it is possible to recover potable alcohol from denatured spirits and articles made with denatured spirits, a comprehensive system of controlling denatured spirits and articles made with denatured spirits is imposed by the IRC at 26 U.S.C. 5271–5275. In order to protect the revenue and public safety, these IRC sections and their implementing regulations in 27 CFR part 20 require an application and permit to withdraw and use specially denatured spirits, and require formulas, recordkeeping, reporting, and other operational procedures.

Affected Public: Businesses or other for-profits; Not-for-profit institutions; State, local or tribal governments.

Estimated Total Annual Burden Hours: 1,890.

OMB Control Number: 1513–0071.

Type of Review: Revision of a currently approved collection.

Title: Tobacco Products Importer or Manufacturer—Records of Large Cigar Wholesale Prices (TTB REC 5230/1).

Abstract: The IRC, at 26 U.S.C. 5701, imposes a federal excise tax on large cigars based on a percentage of the price for which such cigars are sold by the manufacturer or importer. Pursuant to the authority provided by the IRC at 26 U.S.C. 5741 to require recordkeeping, TTB has prescribed by regulation that manufacturers and importers maintain a list of large cigar sale prices. This provides TTB a means of verifying that the correct amount of tax was determined and ultimately paid by the manufacturer or importer of large cigars.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 699.

OMB Control Number: 1513–0127.

Type of Review: Revision of a currently approved collection.

Title: Petitions to Establish or Modify American Viticultural Areas.

Abstract: Under the Federal Alcohol Administration Act at 27 U.S.C. 205(e), TTB regulates the use of applications of origin on wine labels, including the use of American viticultural area (AVA) names. Based on petitions submitted by interested parties, TTB establishes new AVAs or modifies existing AVAs through the rulemaking process. The TTB regulations in 27 CFR part 9 specify the information that must be included in such petitions so that TTB is able to evaluate the petitioner's proposal and determine if it meets TTB's regulatory requirements for creating a new AVA or amending the name, boundary, or other terms of an existing AVA.

Affected Public: Businesses or other for-profits; Farms.

Estimated Total Annual Burden Hours: 1,950.

OMB Control Number: 1513–NEW.

Type of Review: New collection (request for a new OMB control number).

Title: Alternate Method—Automated Commercial Environment (ACE) and Partner Government Agency Message Set for Imports Regulated by the

Alcohol and Tobacco Tax and Trade Bureau.

Abstract: TTB administers several provisions of the U.S. Code that relate to the importation of alcohol beverages, industrial spirits, tobacco products, processed tobacco, and cigarette papers and tubes. The International Trade Data System (ITDS) is an interagency program to establish a single electronic access point through which importers and exporters may submit the data required by Federal government agencies for importation and exportation. The Security and Accountability for Every Port Act (SAFE Port Act) (Pub. L. 109–347) of 2006 mandated participation in ITDS for all agencies that require documentation for clearing or licensing the importation and exportation of cargo.

The Automated Commercial Environment (ACE) provides a ''single window'' that allows importers and exporters to enter one set of data for each shipment of imported or exported goods. The TTB Partner Government Agency (PGA) Message Set defines the TTB-specific information that importers may submit electronically through ACE to meet TTB requirements.

With regard to imports, TTB intends to issue an alternate method to allow importers to submit the TTB PGA Message Set electronically, in lieu of submitting paper documents to U.S. Customs and Border Protection (CBP) at importation. This information collection covers the data that would be submitted electronically through ACE under that alternate method. Most of the information that the alternate method will require importers to submit through ACE is already required by TTB's regulations. However, there are some additional requirements. For example, importers who are required to have a TTB permit number will submit their TTB permit number when filing electronically in ACE. In general, importers of TTB-regulated commodities are required to obtain a permit from TTB, but they have not previously been required by regulation to file that number with CBP. The information collected under this information collection appears in the ''ACE Filing Instructions for TTB-Regulated Commodities'' available at *www.cbp.gov.*

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 36,838.

Brenda Simms,

Treasury PRA Clearance Officer.

[FR Doc. 2016–17875 Filed 7–27–16; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

July 25, 2016.

The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

DATES: Comments should be received on or before August 29, 2016 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimates, or any other aspect of the information collections, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8117, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained by emailing *PRA@treasury.gov,* calling (202) 622–1295, or viewing the entire information collection request at *www.reginfo.gov.*

Internal Revenue Service (IRS)

OMB Control Number: 1545–0096.

Type of Review: Extension of a currently approved collection.

Title: Dividend Equivalents from Sources within the United States REG–120282–10 (TD 9734) & Forms 1042, 1042–S and 1042–T.

Form: Forms 1042, 1042–S, 1042–T.

Abstract: Form 1042 is used to report tax withheld under chapter 3 of the Internal Revenue Code (IRC) on certain income of foreign persons, including nonresident aliens, foreign partnerships, foreign corporations, foreign estates, and foreign trusts; tax withheld under chapter 4 on withholdable payments; tax withheld pursuant to Code section 5000C on specified federal procurement payments; and payments that are reported on Form 1042–S under chapters 3 or 4. Form 1042–T is used to transmit paper Forms 1042–S, Foreign Person's U.S. Source Income Subject to Withholding, to the IRS.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 2,945,594.

OMB Control Number: 1545–0145.

Type of Review: Extension of a currently approved collection.

Title: Notice to Shareholder of Undistributed Long-Term Capital Gains.

Form: Form 2439.

Abstract: Form 2439 is used to provide shareholders of a regulated investment company (RIC) or a real estate investment trust (REIT) the amount of undistributed long-term capital gains.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 29,995.

OMB Control Number: 1545–0160.

Type of Review: Extension of a currently approved collection.

Title: Form 3520–A, Annual Information Return of Foreign Trust With a U.S. Owner.

Form: Form 3520–A.

Abstract: Form 3520–A is the annual information return of a foreign trust with at least one U.S. owner. The form provides information about the foreign trust, its U.S. beneficiaries, and any U.S. person who is treated as an owner of any portion of the foreign trust under the grantor trust rules (as described in IRC sections 671 through 679).

Affected Public: Individuals or households.

Estimated Total Annual Burden Hours: 21,700.

OMB Control Number: 1545–0755.

Type of Review: Extension of a currently approved collection.

Title: Related Group Election With Respect to Qualified Investments in Foreign Base Company Shipping Operations.

Abstract: Treasury Decision (TD) 7959 contains final income tax regulations relating to the election made by a related group to determine foreign base company shipping income and qualified investments in foreign base company shipping operations on a related group basis. The information collection involves the requirement for a U.S. shareholder to provide a statement to make the election.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 205.

OMB Control Number: 1545–1341.

Type of Review: Reinstatement of a previously approved collection.

Title: TD 8619 (Final) (EE–43–92l) Direct Rollovers and 20-Percent Withholding Upon Eligible Rollover Distributions From Qualified Plans.

Abstract: TD 8619 contains final regulations relating to eligible rollover distributions from tax-qualified retirement plans and section 403(b) annuities.

Affected Public: Individuals or households.

Estimated Total Annual Burden Hours: 643,369.

OMB Control Number: 1545–1450.

Type of Review: Extension of a currently approved collection.

Title: Debt Instructions With Originals Issue Discount; Contingent Payments; Anti-Abuse Rule (TD 8674).

Abstract: The collections of information contained in the final regulations in TD 8674 are required to determine a taxpayer's interest income or deductions on a contingent payment debt instrument.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 89,000.

OMB Control Number: 1545–1660.

Type of Review: Reinstatement of a previously approved collection.

Title: Notice 99–43, Nonrecognition Exchanges under Section 897.

Abstract: The collections of information required by this notice are in Temp. Reg. § 1.897–6T(a)(1) and 1.897–5T(d)(1)(iii), Treas. Reg. § 1.1445–2(d)(2)(i)(A) and Temp. Reg. § 1.1445–9T. This information will be used to obtain exemptions from tax under certain nonrecognition transactions and to satisfy reporting requirements regarding these nonrecognition transactions. This information will be used by the IRS to verify whether a taxpayer is entitled to exemption from tax under a nonrecognition transaction.

Affected Public: Individuals or households; Businesses or other for-profits.

Estimated Total Annual Burden Hours: 200.

Brenda Simms,

Treasury PRA Clearance Officer.

[FR Doc. 2016–17885 Filed 7–27–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Solicitation of Nominations for Appointment to the Research Advisory Committee on Gulf War Veterans' Illnesses

ACTION: Notice.

SUMMARY: The Department of Veterans Affairs (VA), Veterans Health Administration (VHA), is seeking nominations of qualified candidates to be considered for appointment as a member of the Research Advisory Committee on Gulf War Veterans' Illnesses (hereinafter referred to as "the Committee"). The Committee was established pursuant to Public Law 105–368, Section 104, to provide advice to the Secretary of Veterans Affairs (Secretary) on the proposed research studies, plans, and strategies related to understanding and treating the health consequences of military service in the Southwest Asia theatre of operations during the 1990–1991 Gulf War. In accordance with the statute and the Committee's current charter, the majority of the membership shall consist of non-Federal employees, appointed by the Secretary from the general public, serving as Special Government employees. The Committee provides, not later than December 1 of each year, an annual report summarizing its activities for the preceding year. The Secretary appoints Committee members for a period of 2 to 3 years. A term of service for any member may not exceed 3 years, but the Secretary may reappoint a member for an additional term of service. Self-nominations and nominations of non-Veterans will be accepted. Any letters of nomination from organizations or other individuals should accompany the package when it is submitted.

In accordance with recently revised guidance regarding the ban on lobbyists serving as members of advisory boards and commissions, Federally-registered lobbyists are prohibited from serving on Federal advisory committees in an individual capacity. Additional information regarding this issue can be found at: *www.federalregister.gov/articles/2014/08/13/2014-19140/revised-guidance-on-appointment-of-lobbyists-to-federal-advisory-committees-boards-and-commissions.*

DATES: Nominations for membership on the Committee must be received no later than 5:00 p.m., Eastern Standard Time, on August 15, 2016.

ADDRESSES: All nominations should be mailed to Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue NW., (10P9), Washington, DC 20420, emailed to *victor.kalasinsky@va.gov,* or faxed to (202) 495–6155.

FOR FURTHER INFORMATION CONTACT: Dr. Victor Kalasinsky, Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue NW., (10P), Washington, DC 20420, telephone (202) 443–5600. (This is not a toll free number.) A copy of the Committee's charter and list of the current membership can be obtained by contacting Dr. Kalasinsky or by accessing the Web site: *http://www.va.gov/rac-gwvi/.*

SUPPLEMENTARY INFORMATION: VHA is requesting nominations for upcoming vacancies on the Committee. The Committee is currently composed of 16 members. The members of the Committee are appointed by the Secretary from the general public, including but not limited to:

(1) Gulf War Veterans;

(2) Representatives of such Veterans;

(3) Members of the medical and scientific communities representing disciplines such as, but not limited to, epidemiology, immunology, environmental health, neurology, and toxicology.

To the extent possible, the Secretary seeks members who have diverse professional and personal qualifications. We ask that nominations include information of this type so that VA can ensure a balanced Committee membership.

The Committee meets at least once and up to three times annually. In accordance with Federal Travel Regulation, Committee members will receive travel expenses and a per diem allowance for any travel made in connection with duties as members of the Committee.

Nomination Package Requirements: Nominations must be typed (12 point font) and include: (1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (*i.e.,* specific attributes which qualify the nominee for service in this capacity), and a statement from the nominee indicating that he/she is a U.S. citizen and is willing to serve as a member of the Committee; (2) the nominee's contact information, including name, mailing address, telephone numbers, and email address; and (3) the nominee's resume or curriculum vitae that is no more than four pages in length. The cover letter must summarize: The nominee's interest in serving on the Committee and contributions she/he can make to the work of the Committee; any relevant Veterans service activities she/he is currently engaged in; the military branch affiliations and timeframe of military service (if applicable). To promote a balanced membership, please provide information about the nominee's personal and professional qualifications and background that would give her/him a diverse perspective on Gulf War Veterans' matters. Finally, please include in the cover letter a statement confirming that she/he is not a Federally-registered lobbyist. The resume should show professional work experience, and Veterans service involvement, especially service that involves Gulf War Veterans' issues.

VA makes every effort to ensure that the membership of its advisory committees is fairly balanced in terms of points of view represented and the Committee's function. Appointments to this Committee shall be made without discrimination based on a person's race, color, religion, sex, sexual orientation, gender identity, national origin, age, disability, or genetic information. Nominations must state that the nominee appears to have no conflict of interest that would preclude membership. An ethics review is conducted for each selected nominee.

Dated: July 25, 2016.

Jelessa M. Burney,

Advisory Committee Management Officer.

[FR Doc. 2016–17873 Filed 7–27–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

National Research Advisory Council

National Research Advisory Council; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C., App. 2, that the National Research Advisory Council will hold a meeting on Wednesday, September 7, 2016, in Room 730 at 810 Vermont Ave. NW., Washington, DC. The meeting will convene at 9:00 a.m. and end at 3:30 p.m., and is open to the public. Anyone attending must show a valid photo ID to building security and be escorted to the meeting. Please allow 15 minutes before the meeting begins for this process.

The agenda will include reviews of the recommendations of the sub-committees on the Air Force Health Study and the Tech Transfer Program. A visit from the SECVA is possible.

No time will be allocated at this meeting for receiving oral presentations from the public. Members of the public wanting to attend, or needing further information may contact Pauline Cilladi-Rehrer, Designated Federal Officer, ORD (10P9), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, at (202) 443–5607, or by email at *pauline.cilladi-rehrer@va.gov.* at least 5 days prior to the meeting date.

Dated: July 25, 2016.

Jelessa M. Burney,

Advisory Committee Management Officer.

[FR Doc. 2016–17886 Filed 7–27–16; 8:45 am]

BILLING CODE P

FEDERAL REGISTER

Vol. 81 Thursday,
No. 145 July 28, 2016

Part II

Farm Credit Administration

12 CFR Parts 607, 611, 614, *et al.*

Regulatory Capital Rules: Regulatory Capital, Implementation of Tier 1/Tier 2 Framework; Final Rule

FARM CREDIT ADMINISTRATION

12 CFR Parts 607, 611, 614, 615, 620, 624, 627 and 628

RIN 3052–AC81

Regulatory Capital Rules: Regulatory Capital, Implementation of Tier 1/Tier 2 Framework

AGENCY: Farm Credit Administration.

ACTION: Final rule.

SUMMARY: The Farm Credit Administration (FCA or we) is adopting a final rule that revises our regulatory capital requirements for Farm Credit System (System) institutions to include tier 1 and tier 2 risk-based capital ratio requirements (replacing core surplus and total surplus requirements), a tier 1 leverage requirement (replacing a net collateral requirement for System banks), a capital conservation buffer and a leverage buffer, revised risk weightings, and additional public disclosure requirements. The revisions to the risk weightings include alternatives to the use of credit ratings, as required by section 939A of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

DATES: *Effective date:* January 1, 2017.

FOR FURTHER INFORMATION CONTACT: J.C. Floyd, Associate Director, Finance and Capital Markets Team, Timothy T. Nerdahl, Senior Policy Analyst—Capital Markets, or Jeremy R. Edelstein, Senior Policy Analyst, Office of Regulatory Policy, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4414, TTY (703) 883–4056; or Rebecca S. Orlich, Senior Counsel, or Jennifer A. Cohn, Senior Counsel, Office of General Counsel, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4020, TTY (703) 883–4056.

SUPPLEMENTARY INFORMATION:

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Addendum: Discussion of the Final Rule

I. Introduction

A. Objectives of the Final Rule

The FCA's objectives in adopting this final rule are:

- To modernize capital requirements while ensuring that institutions continue to hold enough regulatory capital to fulfill their mission as a Government-sponsored enterprise (GSE);
- To ensure that the System's capital requirements are comparable to the Basel III framework and the standardized approach that the Federal banking regulatory agencies have adopted, but also to ensure that the rules take into account the cooperative structure and the organization of the System;
- To make System regulatory capital requirements more transparent; and
- To meet the requirements of section 939A of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (Dodd-Frank Act).

B. Summary of the Proposed Rule

On September 4, 2014, the FCA published in the **Federal Register** a notice of proposed rulemaking seeking public comment on revisions to our regulatory capital requirements governing System banks,[1] System associations, the Farm Credit Leasing Services Corporation, and any other FCA-chartered institution the FCA determines should be subject to this rule (collectively, System institutions).[2] The proposed rule, where appropriate, was comparable to the capital rules published in October 2013 and April 2014 by the Federal banking regulatory agencies[3] for the banking organizations they regulate (U.S. rule).[4] Those rules follow the Basel Committee on Banking Supervision's (BCBS or Basel Committee) document entitled "Basel III: A Global Regulatory Framework for More Resilient Banks and Banking Systems" (Basel III), including subsequent changes to the BCBS's capital standards and BCBS consultative papers, and our proposed rule followed Basel III as appropriate for cooperatives.[5]

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[1] For purposes of this preamble and part 628, as well as some of the regulations in which there are conforming changes and other existing regulations, the term "System bank" includes Farm Credit Banks, agricultural credit banks, and banks for cooperatives. It has the same meaning as "Farm Credit bank", which is defined in § 619.9140 and will continue to be used in some of the regulations in which there are conforming changes as well as in other existing regulations. The Farm Credit Act of 1971, as amended (Farm Credit Act or Act), uses the term "System bank" in a number of its provisions.

[2] 79 FR 52814 (September 4, 2014).

The proposed rule was intended to:

- Improve the quality and quantity of System institutions' capital and enhance risk sensitivity in calculating risk weighted assets,
- Provide a more transparent picture of System institutions' capital to the investment-banking sector, which could facilitate System institutions' securities offerings to third-party investors, and
- Comply with section 939A of the Dodd-Frank Act[6] by proposing alternatives to credit ratings for calculating risk weighted assets for certain exposures that are currently based on the ratings of nationally recognized statistical rating organizations (NRSROs).

After the worldwide financial crisis that began in 2008, the BCBS issued the Basel III framework and has continued to issue additional standards, with the goal of strengthening financial organizations' capital. The U.S. rule reflects Basel III as well as aspects of Basel II and other BCBS standards. The provisions of the U.S. rule that are not specifically included in the Basel III framework are generally consistent with the goals of the framework.

The FCA's proposed rule was comparable to the standardized approach rules of the Federal banking regulatory agencies to the extent appropriate for the System's cooperative structure and status as a GSE with a mission to provide a dependable source of credit and related services for agriculture and rural America. Consistent with the U.S. rule, the FCA's proposed rule incorporated key aspects of the Basel III tier 1 and tier 2 framework and included the following minimum risk-based ratios:

- CET1 capital of 4.5 percent;
- Tier 1 capital of 6 percent; and
- Total capital of 8 percent.

The risk-based minimum ratios are identical to the ratios in the U.S. rule. In contrast to Basel III and the U.S. rule, we did not include all accumulated other comprehensive income (loss) (AOCI) in CET1. We note, however, that under the final U.S. rule, qualifying commercial banks can elect to opt-out of including AOCI in their regulatory capital ratios. We also proposed a tier 1 leverage ratio of 5 percent, of which at least 1.5 percent must be unallocated retained earnings (URE) and URE equivalents (nonqualified allocated surplus that is never revolved). Our proposal differed from the U.S. rule's minimum tier 1 leverage ratio of 4 percent with no minimum URE requirement.

We proposed a capital conservation buffer of 2.5 percent to enhance the resilience of System institutions, the same capital conservation buffer as in the U.S. rule. Our proposed capital conservation buffer similarly had a phase-in period of 3 years, but we did not propose to incorporate any of the other transition periods in Basel III and the U.S. rule.

The proposed rule imposed some new patronage refund and equity redemption requirements, including FCA prior approvals, on System institutions to provide comparability with the U.S. rule and also to ensure the stability and permanence of the capital includable in the tier 1 and tier 2 capital ratios. We proposed that System institutions must retain equities included in CET1 capital for at least 10 years and retain equities included in tier 2 capital for at least 5 years, unless the FCA grants prior approval to redeem or revolve at an earlier date. We proposed to require institutions to adopt a bylaw committing the institutions to the minimum redemption and revolvement periods. We provided a "safe harbor," or deemed prior approval, for cash patronage refund payments and equity redemptions and revolvements as long as the dollar amount of the institution's CET1 capital was equal to or above the dollar amount of the institution's CET1 on the same date of the previous year. Both the Basel III framework and the U.S. rule and applicable law have similar prior approval requirements, but we adapted these requirements to the System's cooperative structure and operations.

The proposed rule contained regulatory deductions and adjustments in the capital ratio calculations that are comparable in purpose to those required in Basel III and the U.S. rule. However, we modified the deductions and adjustments in consideration of the two-tiered, financially interdependent, cooperative structure of the System. We proposed to require deductions from CET1 of goodwill and other intangibles and of allocated equity investments in other System institutions, service corporations, and the Funding Corporation. We also proposed to require System institutions that have purchased equity investments in other System institutions to deduct the investment using the corresponding deduction approach. A "haircut" deduction of a portion of allocated equities was required if an institution redeemed or revolved equities before the end of the applicable minimum redemption or revolvement period.

We proposed a limit on how much third-party capital—capital held by investors other than other System institutions or their member-borrowers—could count in the regulatory capital ratios. The proposed limit was similar to the limit the FCA had previously imposed on System institutions on a case-by-case basis.

The FCA also proposed changes to its risk-based capital rules for determining risk weighted assets—that is, the calculation of the denominator of a System institution's risk-based capital ratios. We proposed to eliminate the credit ratings of NRSROs from risk weights for certain exposures, consistent with section 939A of the Dodd-Frank Act. As an alternative, FCA proposed to include methodologies for determining risk weighted assets for exposures to sovereigns, foreign banks, and public sector entities, securitization exposures, and counterparty credit risk. We proposed an increased risk-weight for high-volatility commercial real estate (HVCRE) exposures and for past due and nonaccrual exposures. We did not propose to alter FCA Bookletter BL–053, which since 2007 has permitted lower risk weights for certain exposures to generation and transmission and electric distribution cooperatives (electric cooperatives), but we also did not propose to include the lower risk weights in the rule. We proposed to increase the credit conversion factors (CCF) that apply to unused commitments, including commitments from System banks to associations to fund direct loans. We proposed to eliminate the existing 50-percent risk weight for certain other financing institutions (OFIs). We proposed certain due diligence requirements in connection with securitization exposures. The proposed rule included new risk weights for cleared transactions, guarantees including credit derivatives, collateralized financial transactions, unsettled transactions, and securitization exposures.

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[3] The Federal banking regulatory agencies are the Office of the Comptroller of the Currency (OCC), the Board of Governors of the Federal Reserve System (FRB), and the Federal Deposit Insurance Corporation (FDIC).

[4] 78 FR 62018 (October 11, 2013) (final rule of the OCC and the FRB); 79 FR 20754 (April 14, 2014) (final rule of the FDIC).

[5] Basel III was published in December 2010 and revised in June 2011. The text is available at *http://www.bis.org/publ/bcbs189.htm.* The BCBS was established in 1974 by central banks with bank supervisory authorities in major industrial countries. The BCBS develops banking guidelines and recommends them for adoption by member countries and others. BCBS documents are available at *http://www.bis.org.* The FCA does not have representation on the Basel Committee, as do the Federal banking regulatory agencies, and is not required by law to follow the Basel standards.

[6] Public Law 111–203, 124 Stat. 1376 (2010).

We generally did not propose risk weightings for exposures that System institutions have no authority to acquire.[7] In some but not all cases, we discussed in the preamble this variance from the rules of the Federal banking regulatory agencies. In addition, we did not propose risk weightings for certain exposures that are both complex and unlikely; we stated that we would determine the treatment on a case-by-case basis using our regulatory reservation of authority. We generally discussed these exposures in the preamble. We reminded System institutions that the presence of a particular risk weighting does not itself provide authority for a System institution to have an exposure to that asset or item. System authorities to acquire exposures are contained in other provisions of our regulations and in the Farm Credit Act.

We did not propose to adopt the "advanced approaches" regulatory capital rules because no System institution has the volume of assets or foreign exposures that would subject it to those approaches if it were regulated by a Federal banking regulatory agency.[8] We also did not propose the market risk requirements, because no System institution has significant exposure to market risk.

The proposed rule also required additional recordkeeping and disclosures by System banks, comparable to the required disclosures in the U.S. rule for commercial banks with assets of $50 billion and above. It was our belief that the benefits to the System of these proposed rules would more than outweigh the requirements and additional responsibilities we would require.

We proposed to: (1) Place the tier 1 and tier 2 risk weighted and leverage capital requirements in a new part 628 of FCA regulations in title 12 of the Code of Federal Regulations: (2) rescind the risk-weighting provisions in subpart H of part 615 and the core surplus, total surplus, and net collateral requirements in subpart K of part 615; (3) retain in part 615 the requirements for the numerator of the permanent capital ratio, a measure that is mandated by the Farm Credit Act, but make the risk weightings for the denominator of the permanent capital ratio the risk weightings in new part 628; and (4) make conforming changes in other FCA regulations.

In the proposed rule, we used the general format and the section and paragraph numbering system of the U.S. rule to the extent possible. In many cases, we retained the numbering system by reserving sections and paragraphs where we did not propose parallel provisions. We did so in order to facilitate the comparison of the proposal with the U.S. rules.

C. Summary of the Final Rule

The final rule replaces the FCA's core surplus, total surplus, and net collateral rules with common equity tier 1 (CET1), tier 1, total capital, capital conservation buffer, and leverage buffer rules as described below. The final rule also revises the risk weightings in the existing rule and makes minor adjustments to the permanent capital calculation. In addition, it expands public disclosure requirements for System banks. After considering the comments we received, we have made changes in the final rule to address policy, technical, and compliance concerns raised by commenters.

In the final rule, we have adopted the minimum CET1, tier 1, and total risk-based capital ratios as set forth in the proposed rule. We have adopted a lower tier 1 leverage ratio of 4 percent in the final rule but have retained the URE and URE equivalents requirement of 1.5 percent, and we have added a tier 1 leverage buffer of 1 percent.

We have adopted the capital conservation buffer of 2.5 percent as proposed and have provided a phase-in period of 3 years that will end on December 31, 2019.

We have revised a number of the proposed patronage refund and equity redemption or revolvement requirements:

- We have revised the minimum CET1 redemption or revolvement period to 7 years from 10 years in the proposal but have adopted the other minimum periods as proposed.
- We have provided that institution boards may adopt a resolution annually that commits the institutions to comply with the minimum redemption and revolvement periods, as an alternative to adopting a capital bylaw.
- We have expanded the "safe harbor" to exempt 3 types of equity redemptions or revolvements from the applicable minimum holding periods: (1) Equities mandated to be redeemed or retired by a final order of a court of competent jurisdiction; (2) equities belonging to the estate of a deceased former borrower; and (3) equities that the institution is required to cancel under § 615.5290 of our regulations.

We have adopted the regulatory deductions and adjustments in the final rule as proposed, with several exceptions. We have revised the 30-percent mandatory "haircut" for noncompliance with the minimum revolvement periods and have replaced it with a provision stating that the FCA may take a supervisory or enforcement action for noncompliance with the minimum revolvement periods, which may include requiring an institution to deduct a portion of its equities from CET1 capital.

We have simplified the calculation for the third-party capital limit.

We have not finalized the proposed provisions governing HVCRE at this time. We have not included lower risk weights for exposures to electric cooperatives in the rule, but FCA Bookletter BL–053 remains in effect. We have applied a 20-percent CCF to all unused commitments from System banks to fund direct loans without regard to maturity, rather than applying a 50-percent CCF to commitments longer than 14 months, and we have clarified that this capital treatment applies to direct loan commitments to OFIs as well as associations. We have retained the existing, but not proposed, 50-percent risk weight for loans to certain OFIs, but we have eliminated the credit rating standard for this risk weight. We have retained the higher risk weight for past due and nonaccrual exposures and the due diligence requirements for securitization exposures. We have revised the definition of Government-sponsored enterprise (GSE) to include the System.

We have adopted the recordkeeping disclosure requirements for System banks as proposed.

We have adopted conforming changes to existing FCA regulations.

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[7] However, we did propose risk weighting for exposures that System institutions are not permitted to acquire under their investment authorities, because such exposures could be acquired through foreclosures on collateral or similar transactions.

[8] In general, the advanced approaches rule applies to banks with consolidated total assets of at least $250 billion or with foreign exposures of $10 billion or more. Only two System institutions have total assets in excess of $50 billion, and foreign exposures are negligible.

TABLE 1—SUMMARY OF KEY PROVISIONS OF THE TIER 1/TIER 2 CAPITAL ITEMS AND STANDARDIZED APPROACH RISK WEIGHTS

Minimum capital ratios	Treatment in final rule
Tier 1/Tier 2—Capital Items	
Common equity tier 1 (CET1) capital ratio (§ 628.10)	A minimum requirement of 4.5 percent.
Tier 1 capital ratio (§ 628.10)	A minimum requirement of 6.0 percent.
Total capital ratio (§ 628.10)	A minimum requirement of 8.0 percent.
Tier 1 Leverage ratio (§ 628.10)	A minimum tier 1 leverage ratio requirement of 4.0 percent of which at least 1.5 percent must consist of unallocated retained earnings and unallocated retained earnings equivalents. Applies to all System institutions.
Components of Capital and Eligibility Criteria for Regulatory Capital Instruments (§§ 628.20, 628.21, and 628.22).	Describes the eligibility criteria for regulatory capital instruments and adds certain adjustments to and deductions from regulatory capital.
Capital Conservation Buffer and Leverage Buffer Amounts (§ 628.11)	A 2.5-percent capital conservation buffer of CET1 capital above the minimum risk-based capital requirements and a 1-percent leverage buffer of tier 1 capital above the minimum capital requirement, both of which must be maintained to avoid restrictions on capital distributions and certain discretionary bonus payments.
Risk weighted Assets—Standardized Approach	
Credit exposures to:	Remains unchanged from existing regulations:
U.S. government and its agencies	0 percent.
U.S. depository institutions and credit unions (including those that are OFIs).	20 percent.
U.S. public sector entities, such as states and municipalities	20 percent—general obligations.
Cash	50 percent—revenue obligations.
Cash items in the process of collection	0 percent.
Exposures to other System institutions that are not deducted from capital.	20 percent.
Assets not specifically assigned to a risk weight category and not deducted from capital.	100 percent.
(§ 628.32)	100 percent.
Exposures to certain supranational entities and multilateral development banks (§ 628.32).	Assigned a 0 percent risk weight (reduced from 20 percent).
Exposures to Government-sponsored enterprises (§ 628.32)	Non-System exposures: Risk weight for preferred stock increased from 20 percent to 100 percent. Risk weight for all other exposures (except equity exposures, which are discussed below) remains at 20 percent. System exposures: Risk weight for direct loans remains at 20 percent. All equities, including preferred stock, deducted from capital (not risk weighted).
Credit exposures to:	
Foreign sovereigns; Foreign banks; Foreign public sector entities (§ 628.32)	Assigns risk-sensitive risk weights based on the Country Risk Classification measure produced by the Organization for Economic Cooperation and Development (risk weight no longer determined based on OECD membership status).
Corporate exposures (§ 628.32)	Assigns a 100-percent risk weight to most corporate exposures, including exposures to agricultural borrowers and to OFIs that do not satisfy the criteria for a 20-percent or 50-percent risk weight. Assigns a 50-percent risk weight to non-depository institution/non-credit union OFIs that are investment grade or that meet standards similar to OFIs that qualify for a 20-percent risk weight.
Residential mortgage exposures (§ 628.32)	50 percent for first lien residential mortgage exposures that satisfy specified underwriting criteria. 100 percent otherwise.
High volatility commercial real estate exposures (§ 628.32)	Provisions assigning higher risk weight not adopted in this rulemaking. Additional rulemaking or guidance may take place in future.
Past due and nonaccrual exposures (§ 628.32)	Assigns a 150-percent risk weight to exposures that are past due or in nonaccrual status, unless they are residential mortgage exposures or they are guaranteed or secured by financial collateral.
Off-balance Sheet Items (§ 628.33)	Certain credit conversion factors (CCF) revised, including the CCF for unused short-term commitments that are not unconditionally cancellable, which is increased from 0 percent to 20 percent.
OTC Derivative Contracts (does not include cleared transactions) (§ 628.34).	Modifies derivative matrix table slightly. Recognizes credit risk mitigation of collateralized OTC derivative contracts.
Cleared Transactions (§ 628.35)	Provides preferential capital requirements for cleared derivative and repo-style transactions (as compared to requirements for non-cleared transactions) with central counterparties that meet specified standards.
Guarantees and Credit Derivatives (§ 628.36)	Provides a more comprehensive recognition of guarantees.
Collateralized Transactions (§ 628.37)	Recognizes financial collateral.
Unsettled Transactions (§ 628.38)	Risk weight depends on number of business days past settlement date.

TABLE 1—SUMMARY OF KEY PROVISIONS OF THE TIER 1/TIER 2 CAPITAL ITEMS AND STANDARDIZED APPROACH RISK WEIGHTS—Continued

Minimum capital ratios	Treatment in final rule
Securitization Exposures (§§ 628.41, 628.42, 628.43, 628.44, and 628.45).	Replaces the ratings-based approach with either the standardized supervisory formula approach (SSFA) or the gross-up approach for determining a securitization exposure's risk weight based on the underlying assets and exposure's relative position in the securitization's structure.
Equity exposures (§§ 628.51, 628.52, and 628.53)	Establishes a more risk-sensitive treatment for equity exposures.
Disclosure Requirements (§§ 628.61, 628.62, and 628.63)	Establishes qualitative and quantitative disclosure requirements, including regarding regulatory capital instruments, for all System banks.
Existing FCA Regulatory Capital	
Minimum Capital Ratios:	
Permanent capital ratio (§§ 615.5201 and 615.5205)	Numerator calculation remains unchanged, but risk weights (denominator) are revised.
Total surplus ratio (§§ 615.5301(i) and 615.5330(a))	Eliminated.
Core surplus ratio (§§ 615.5301(b) and 615.5330(b))	Eliminated.
Net collateral Ratio (banks only) (§§ 615.5301(d) and 615.5335)	Eliminated.

D. Comments on the Proposed Rule

The original comment period for the proposed rule was for 120 days, ending on January 2, 2015. At the request of the System, on December 23, 2014, the FCA extended the comment period to February 16, 2015,[9] and on June 23, 2015 the FCA reopened the comment period for a 15-day period between June 26 and July 10, 2015.[10]

The FCA received approximately 2400 public comments on the proposed rule. Nearly 500 of the comments were from individual System associations and their directors and officers; the 4 System banks; and the Farm Credit Council, a trade association representing the interests of System institutions. Approximately 1800 member-borrowers of one System association submitted comments.[11] We also received a comment letter from a member of Congress on behalf of several of his constituents. The comment letter submitted by the Farm Credit Council (System Comment Letter) states that the System's capital workgroup developed the comments after soliciting input from all System institutions. This input was further discussed and reviewed among the institutions, after which the capital workgroup circulated a draft comment letter for further review.[12] The System Comment Letter is comprehensive and detailed, covering most or all of the numerous regulatory philosophy, policy and technical issues directly and indirectly addressed in the proposed rule. Because the System Comment Letter was developed with input of all System institutions, the FCA focuses primarily on addressing those comments in this preamble. The preamble also addresses the individual comment letters of System institutions and their members and representatives, as well as those of non-System commenters, that contain substantially different arguments or discuss other issues.

In addition, 3 comments were from non-System agricultural lenders with lending relationships with System banks (other financing institutions or OFIs). Approximately 70 rural electric cooperatives and a trade association representing rural electric cooperatives submitted comments. Each of these two groups of commenters submitted a comment regarding the single issue of the proposed risk-weightings of System institutions' exposures to their particular business.

We also received comments from several educational and trade associations promoting the interests of farmers and farm businesses, cooperative businesses, rural electric cooperatives, and U.S. community bankers. The farm-related and cooperative trade associations all submitted a general comment supporting the System Comment Letter. They urged the FCA not to adopt regulations that would diminish the democratic nature of cooperatives, their unique governance structure, and their ability to maintain financial and ethical integrity. The trade association representing community banks expressed concern about some provisions of the U.S. rule as applied to community banks and generally recommended the imposition of more strenuous capital requirements on System institutions. The trade association asserted that 1) there was an implicit government guarantee of the debt and equity of System institutions that the Basel III framework and the proposed rule failed to address, and that 2) this failure put taxpayers at risk for future bailouts, while privately-funded and well-capitalized community banks suffer with higher funding costs and absence of a government backstop. These trade association letters did not include comments on specific aspects or requirements of the proposed rule.

E. Discussion of Threshold Issues Raised in the System Comment Letter

This section of the preamble addresses the issues that the System Comment Letter identified as "Threshold Issues."

1. Basel III, the U.S. Rule, and Cooperative Principles

The System Comment Letter expressed strong support for modernizing the FCA's capital regulations through the adoption of a tiered framework comparable to Basel III and the U.S. rule. The System stated that such a modernization "will be helpful to external investors and others who are acquainted with the Basel III framework and understand the overall financial strength and capital capacity of individual [System] institutions as cooperative financial institutions." The

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[9] *See* 79 FR 76927 (December 23, 2014).

[10] *See* 80 FR 35888 (June 23, 2015). The Farm Credit Council stated that the reason for the System's request was to give System representatives the opportunity to discuss the proposed rule with the FCA Board members that had joined the FCA Board on March 13 and 17, 2015.

[11] The great majority of the comments were the same form letter; however, a number of these commenters added hand-written comments to the form letter.

[12] A number of the comment letters from individual System institutions summarized, were identical to, or closely tracked, the System Comment Letter.

System asserted, however, that the FCA's proposed rule is "far harsher" and, in addition, "discourages the formation, retention, and distribution of member-held equity, undermining cooperative business principles that have been in place for decades." The System further asserted that, "[a]s expected by Basel III, FCA should take into account all principles specific to the constitution and legal structure of cooperatives."

The System Comment Letter is divided into three parts. The first part discusses 9 "threshold" issues important to the System, including a number identified as "undermin[ing] cooperative principles and member participation in the management, ownership, and control of System institutions as required by the Act." The second part, Appendix A, contains comments to specific questions we asked in the preamble to the proposed rule. The third part, Appendix B, identifies "various conceptual and technical issues" that are explained in a discussion of particular aspects of the regulation text. We first address the general assertion that the proposed rule is anti-cooperative as well as the issues identified in the System Comment Letter as "threshold issues." The section that follows discusses the System's remaining comments and other comments that we received.

In proposing the capital rule, it was our intention to implement capital requirements that are comparable to the Basel III framework as embodied in the U.S. rule, with adjustments to take into consideration the structure and operations of System institutions. As the System Comment Letter notes, the Basel III framework's capital components are described by the Basel Committee in terms of the capital of joint-stock banks—that is, financial institutions that issue stock to investors whose objective is to earn a profit. (We note that System institutions, like some other cooperative financial institutions, do issue stock, but they are not joint-stock banks as that term is used by the Basel Committee.) Investors with voting interests in a joint-stock bank are not required to do business with the joint-stock bank in which they own stock, and there is no connection between their ownership interests and any customer relationship they may have with such bank. Cooperatives and mutual associations, unlike joint-stock banks, are not created for the profit of investors but rather for the benefit of their member-borrowers, and there is a close connection between their equity ownership and their customer relationship with the cooperative institution or mutual. The Basel Committee intended the criteria for joint-stock banks also to apply to other banking organizations, as explained in footnote 12 to the Basel III document:

> The criteria also apply to non-joint stock companies, such as mutuals, cooperatives or savings institutions, taking into account their specific constitution and legal structure. The application of the criteria should preserve the quality of the instruments by requiring that they are deemed fully equivalent to common shares in terms of their capital quality as regards loss absorption and do not possess features which could cause the condition of the bank to be weakened as a going concern during periods of market stress. Supervisors will exchange information on how they apply the criteria to non-joint stock companies in order to ensure consistent implementation.

The System Comment Letter appears to interpret this footnote to mean that Basel III-based regulations for cooperatives, such as the FCA's proposed rule, must take account of the "specific constitution and legal structure" of System institutions by deferring to "all cooperative principles" that are inconsistent with the Basel III criteria for joint-stock banks. Such an interpretation is not entirely without basis, given the lack of detail in the footnote, and this may have already have led to greater flexibility than intended by the Basel Committee in some banking agencies' regulatory interpretations. We note that, in December 2014, banking experts appointed by the Basel Committee to assess whether European Union pronouncements and its member countries' regulations comply with the Basel III framework raised concerns about exceptions some countries made to the framework for mutually owned institutions and suggested the Basel Committee consider issuing more specific guidance.[13] The Basel framework provides some clarity in a discussion of strengthening the global capital framework, in which the Basel Committee emphasizes the need for uniform standards for regulatory capital:

> The crisis . . . revealed the inconsistency in the definition of capital across jurisdictions and the lack of disclosure that would have enabled the market to fully assess and compare the quality of capital between institutions.
>
> To this end, the predominant form of Tier 1 capital must be common shares and retained earnings. This standard is reinforced through a set of principles that also can be tailored to the context of non-joint stock companies to ensure they hold comparable levels of high quality Tier 1 capital. Deductions from capital and prudential filters have been harmonized internationally and generally applied at the level of common equity or its equivalent in the case of non-joint stock companies.[14]

The FCA disagrees with the apparent interpretation in the System Comment Letter that the Basel III footnote 12 directs regulators to defer to mutual and cooperative constitutions and legal structures. There are 4 key points in the footnote, as clarified by the discussion in the text of the framework document, that we followed in the proposed rule. First, cooperative capital[15] that is included in CET1 or tier 2 capital must be substantively equivalent in quality to the CET1 or tier 2 capital of joint-stock banks, and that means cooperative capital must be excluded if they are not substantively equivalent. Second, cooperative capital must be excluded if it has features (including features that may be typical of cooperative operations) that weaken the capacity of the institution to continue operations during stressful times. Third, exceptions and adjustments to the criteria are in some cases necessary because of cooperative institutions' legal authorities and mandates, in order to ensure the uniform quality of the components and consistent implementation of the standards. Fourth, consistent implementation of the standards is required to enable the market to compare the quality of capital between institutions. Otherwise, the framework's goal of uniform capital standards among financial institutions would not be achieved—and the FCA could not represent our rule as comparable to Basel III and the U.S. rule. Not being able to represent our rule as comparable would eliminate a primary reason given by the System to modernize the capital regulations—to help third-party investors that are acquainted with the Basel III framework evaluate System institutions' capital.

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[13] See Basel Committee on Banking Supervision, "Regulatory Consistency Assessment Program (RCAP): Assessment of Basel III regulations—European Union," December 2014. Paragraph 1.4.3 states the following, in pertinent part:

CET1 instruments issued by mutually owned institutions: Basel III permits some flexibility in order to accommodate the nature of capital instruments of different mutually owned banks. However, the Assessment Team is concerned that the CRR concessions from the 14 CET1 criteria for mutuals go beyond the permissible flexibility in the Basel standard, while noting that this standard does not precisely define the extent of permissible flexibility. This is an area where the BCBS could provide additional guidance on the extent of flexibility considered appropriate for CET1 issued in mutual bank structures.

In the case of one banking group, the Assessment Team observed that individual instruments of some cooperative banks were being marketed as being redeemable, non-loss absorbing in liquidation, and paying a distribution based on the face value. In the Assessment Team's view, this goes beyond the limits of permissible flexibility in Basel III. The fact that regulatory approval is required for redemption and that redemption may be deferred does not, in the team's opinion, mitigate the public perception that these instruments are redeemable, despite the approval requirements set out in the CRR.

While the amount of such instruments is clearly material for banks with mutual structures, the Assessment Team understands that these are well understood capital structures supported by Member State law that have proven resilient in times of stress. Moreover, some of the internationally active parts of such banking groups are capitalised by common equity in the form of publicly listed ordinary shares, which serves as an alternative source of loss-absorbing capital. This is an area where the Assessment Team believes the Basel Committee could provide additional guidance on the extent of flexibility considered appropriate for CET1 issued in mutual bank structures. As a result, this issue is noted as a deviation, but the Assessment Team has not factored this element into the grade for the definition of capital category nor into the overall assessment grade.

[14] Basel III Framework, paragraphs 8 and 9.

[15] Cooperative capital includes common cooperative equities and preferred stock issued to member-borrowers or other System institutions.

In the proposed rule we made appropriate exceptions and adjustments related to legal authorities, structure and also traditional operations that are cooperative in nature. These include the exception for the liquidation priorities of URE and common cooperative equities; the eligibility requirements to become member-borrowers; the requirement to purchase member stock in order to obtain a loan; the restriction of association voting rights to member-borrowers in agriculture and related businesses and the restriction of bank voting rights to member associations and retail cooperative member-borrowers; the one-member, one-vote mandate for association member-borrowers; and the proportional voting mandate for associations and cooperatives that borrow from System banks. An important difference from joint-stock corporations such as commercial banks is that the voting stockholders, because they are also the customers, want both low interest rates on their loans and high amounts of patronage payments, and they are in a position to pressure the institution to provide patronage payments on a regular basis. Some institutions encourage member expectations by promoting and illustrating patronage payments as a routine "cash-back dividend" that effectively reduces the real interest rate on a member's loan as demonstrated by materials on their Web sites and in press releases.

Our proposed rule also included exceptions and adjustments to take into account non-cooperative differences between System institutions and commercial banks in legal authorities, mandates, and legal structure. Such differences include: (1) The two-tiered structure of System banks supervising and lending to the System associations that own them; (2) the joint and several liability of System banks for almost all the general debt they issue; (3) the GSE status of the System; (4) the limitations on System associations to borrow from financial institutions other than their affiliated System bank; (5) the statutory discretion of a System institution to redeem purchased stock and retire allocated equities; and (6) the requirement that System institution voting members must approve amendments to the capitalization bylaws. Commercial banks have capital-related restrictions, some statutory and some in the U.S. rule, that the Act and our regulations have not previously imposed on System institutions, such as: (1) Restrictions on redemption of equities without both regulatory approval and stockholder approval; (2) restrictions on cash dividend payments without regulatory approval; and (3) prompt corrective action. Restrictions and adjustments in our capital rule, to the extent consistent with the System's GSE status, are also necessary in order to make our regulatory capital framework substantively comparable to the U.S. rule.

We note that the U.S. rule does not have specific provisions for mutual banking organizations.[16] The regulatory capital of these mutuals is made up almost entirely of retained earnings that we understand are never allocated to members; consequently, the retained earnings of mutuals have the same characteristics as the retained earnings of joint-stock banks—and, in our judgment, the URE of System institutions. Because neither joint-stock banks nor mutuals allocate equities, the U.S. rule does not take into consideration the allocation process.[17] In most cases, once a System institution has allocated equities to members, the members acquire ownership attributes that make the earnings stock-like and more appropriately treated like stock than like URE. The distinction is important because, if we treated allocated equities the same way we treat URE, none of the criteria that apply to equities included in tier 1 and tier 2 capital—including minimum revolvement periods and the expectation criterion discussed below—would apply.

2. Treatment of Allocated Equities

The System Comment Letter states that allocated equities are retained earnings and uses the term "allocated retained earnings" throughout its comment, stating that "allocated retained earnings" are the same as URE and should be treated the same way. The System makes a number of additional assertions about Basel III and the U.S. rule. These assertions include:

- Basel III does not establish tiers of retained earnings, does not require deduction from retained earnings of amounts that a commercial bank has announced it plans to distribute, and does not exclude retained earnings from CET1 to reflect market pressures to pay dividends.
- The U.S. rule includes all retained earnings in CET1 even though commercial banks are authorized to distribute retained earnings in amounts up to current year earnings plus net income for the two previous years. If the FCA does not change its position to treat retained earnings differently from the Basel III framework and the U.S. rule, it should impose only criteria applicable solely to retained earnings.
- Basel III and the U.S. rule do not apply any of the CET1 criteria to retained earnings. The FCA's proposed rule inappropriately applies the criteria to "allocated retained earnings," including minimum revolvement periods established in capitalization bylaws.

The System Comment Letter correctly states that Basel III and the U.S. rule fully include "retained earnings" in CET1 and do not apply to retained earnings any of the CET1 criteria they apply to equities. Our treatment of URE is identical to the treatment of "retained earnings" in Basel III and the U.S. rule. In our view, equating URE with the "retained earnings" in Basel III and the U.S. rule is correct because, to our knowledge, all the retained earnings of institutions covered by Basel III and the U.S. rule are unallocated. Our research has not revealed any financial cooperatives or mutuals under the Basel III framework or the U.S. rule that allocate equities. All the System's comments about treatment of retained earnings pertain only to our treatment of earnings that have been allocated to their members. Rather than establishing tiers of retained earnings, a structure the System's comment seems to both criticize and recommend, we treat allocated equities the same way we treat purchased equities, consistent with the provisions of the Act and our existing capital regulations. Most of the System's critical comments about our treatment of allocated equities have to do with the capitalization bylaw requirement and the requirement for prior approval of revolvements of allocated equities that do not fit within the safe harbor ("deemed prior approval") provision. We address these criteria-related comments when we discuss the bylaw and minimum holding period requirements later in this preamble.

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[16] The OCC issued a bulletin in 2014 describing the characteristics of mutuals and discussing supervisory considerations, including capital issues. *See http://www.occ.gov/news-issuances/bulletins/2014/bulletin-2014-35.html.* The OCC's decision not to adopt special provisions for mutuals appears to be due to the fact that the legal authorities do not differ between commercial banks and mutuals in ways that require adjustments to the rule. According to the bulletin, mutual associations are subject to the same laws and regulations as joint-stock banks except for regulations on chartering, bylaws, combinations, and member communications.

[17] When a System institution pays patronage in the form of equities and retains these equities for the benefit of the cooperative institution, this is known as the allocation process in which a member-borrower's name is assigned to those equities.

We address here our basis for treating allocated equities the same way we treat purchased equities. We treat earnings that a System institution has allocated to a member as equities, irrespective of whether the institution calls them allocated equities, allocated stock, allocated surplus, or allocated retained earnings. "Allocated equities" is the term we use in existing capital regulations and also used in the proposed rule. The Act and existing FCA capital regulations most commonly use the term "allocated equities" and treat them as stock; in the Act and our regulations URE is consistently treated differently from stock and allocated equities.

We note that the term "allocated retained earnings" used in the System Comment Letter could potentially confuse third-party investors who are not familiar with the allocation process and may not understand the ownership attributes that attach once the earnings are allocated.[18] In addition, the term is not found in the Act. The closest similar term is in section 4.3A(a)(1) of the Act, which defines permanent capital to include the following: (1) "Current year retained earnings," (2) "allocated and unallocated earnings," (3) "all surplus," (4) stock that is not protected stock and that is not retireable at the discretion of the holder, and (5) other debt or equity instruments that the FCA determines appropriate to be considered permanent capital. "Allocated and unallocated earnings" may appear to be a separate and distinct category, but it overlaps with the categories of "current year retained earnings" and "surplus." "Allocated and unallocated earnings" also expressly overlaps with "stock," because paragraph (a)(2) of section 4.3A, which immediately follows the definition of permanent capital, further defines "stock" to include "voting and nonvoting stock (including preferred stock), equivalent contributions to a guaranty fund, participation certificates, allocated equities, and other forms and types of equities." Other than the single, ambiguous reference to "allocated and unallocated earnings" in section 4.3A(a)(2) of the Act, the System's similar term "allocated retained earnings" is not a term used in the Act or our regulations. It has been rarely, if ever, used in FCA bookletters, informational memoranda, or **Federal Register** preambles.[19]

Many provisions of the Act treat URE and allocated equities in separate ways. Section 4.9A(d) of the Act, which defines and guarantees full repayment of "eligible borrower stock," defines borrower stock to mean "voting and nonvoting stock, equivalent contributions to a guaranty fund, participation certificates, allocated equities, and other similar equities that are subject to retirement under a revolving cycle issued by any System institution and held by any person other than any System institution." URE is not protected under section 4.9A of the Act. Sections 2.6 and 3.10 of the Act establish that associations and CoBank, ACB have liens on the stock and equities, including allocated equities, of their retail borrowers. In section 3.2(a)(2)(A)(ii) of the Act, voting by a bank for cooperatives' retail borrowers is based on a stockholder's proportional equity interest "including allocated, but not unallocated, surplus and reserves." Retirement of stock for a bank for cooperatives as provided in sections 3.5 and 3.21 of the Act treats the retirement of allocated equities the same as the retirement of "issued" equities. In section 6.4 of the Act, which pertains to the Assistance Board's certification of a System institution to obtain financial assistance by issuing preferred stock, allocated equities are treated as stock. Section 6.26(c)(1)(B) of the Act, pertaining to the repayment of financial assistance by the System, bases part of the repayment amount on an institution's amount of URE but not allocated equities.

Existing FCA capital regulations are consistent with the Act's separate treatment of URE and allocated equities. Section 615.5330(b)(1) provides that a portion of core surplus must consist of URE and other includible equities *other than* allocated equities. A provision for banks for cooperatives that was in effect until 1997 required those banks to add at least 10 percent of their net earnings to their unallocated reserve account each year until URE equaled half the minimum permanent capital requirement (3.5 percent of risk weighted assets).[20]

Though the reason for treating allocated equities differently from URE is not expressly stated in the Act, the difference is likely based on the ownership attributes of allocated equities that make allocated equities stock-like in nature. The rule's treatment of allocated equities as stock and its treatment of URE as equivalent to the "retained earnings" in Basel III and the U.S. rule are consistent with the treatment of allocated equities and URE in the Act and existing FCA regulations.

3. Required Minimum Redemption/ Revolvement Periods

The proposed rule provided for minimum redemption and revolvement periods (holding periods) as part of the criteria for including equities in the new regulatory capital components. We proposed a minimum 10-year holding period for inclusion in CET1 capital and a minimum 5-year holding period for inclusion in tier 2 capital. In addition, consistent with Basel III and the U.S. rule, we proposed a 5-year no-call period for inclusion of equities in additional tier 1 capital and tier 2 capital, as well as a minimum 5-year term for term stock includible in tier 2 capital.

The System Comment Letter did not object to the minimum no-call periods or minimum term for term stock but expressed objections to the minimum redemption and revolvement periods as follows:

- The minimum holding period should be eliminated because there is no basis for it in Basel III.
- An allocated equity with an express minimum term of 10 years is no more permanent than an allocated equity that is perpetual on its face.
- The FCA has historically expressed a concern with member pressure on institutions for the payment of patronage or

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[18] A review of recent financial reports shows that some System institutions refer to allocated equities as "allocated retained earnings" in the reports, some institutions use both terms, and other institutions do not use the term "allocated retained earnings." The [Federal Farm Credit Banks] Funding Corporation notably does not use the term "allocated retained earnings" in its Annual and Quarterly Statements that provide information for investors in the debt securities jointly issued by the four System banks.

[19] In a search of FCA databases, we found two instances of a definition of allocated equities as including "allocated retained earnings and allocated stock" in the Capital Management section of the FCA examination manual. We note that, in the preamble to the proposed rule, our Table 2 comparing cooperative capital to the capital of a joint-stock bank incorrectly categorized "allocated surplus" as comparable to retained earnings but categorized allocated stock as comparable to common stock.

[20] This requirement was in previous § 615.5330 and was rescinded in 1997 when the FCA adopted the net collateral ratio for banks. Under that previous regulation, we permitted CoBank, ACB to meet the URE requirement with nonqualified allocated equities, issued to its retail borrowers, that CoBank, ACB had a confirmed plan not to revolve except in liquidation. Such treatment is similar to the "URE equivalents" treatment for the capital conservation buffer in the proposed rule.

redemption of allocated retained earnings. Factually, System institutions do not face greater pressure to distribute allocated equities than the pressure on commercial banks to make dividend payments.

- Several System institutions in the years 2007–2013 suspended cash patronage payments or reduced allocated equity redemptions when they experienced credit and business issues. Loan volume declined in some instances due to more conservative lending practices but not to borrower flight. The institutions resolved their credit and business issues and resumed cash patronage payments and increased allocated equity redemptions. This demonstrates that System institution retained earnings should qualify as CET1 without application of any limiting criteria.
- If FCA remains resolute in treating allocated equities differently from URE, the agency should continue the requirements in existing FCA regulations based on minimum revolvement periods: A plan or practice not to revolve CET1 equities for at least 5 years and not to revolve additional tier 1 equities for at least 3 years, with no minimum revolvement period for tier 2 equities.
- If FCA decides to adopt minimum holding periods as set forth in the proposed rule, a minimum holding period of 7 years for inclusion in CET1 capital would be more workable and reasonable.

The System is correct that Basel III does not include a minimum redemption or revolvement period for CET1 equities or tier 2 equities. Such a minimum holding period is not necessary in the Basel framework or in the U.S. rule because commercial banks must obtain their regulator's approval before redeeming any equities, no matter how many years the equities have been outstanding. System institutions, likewise, will be able to redeem or revolve equities before the holding period ends if the institutions receive FCA approval.[21] What System institutions will be able to do that commercial banks cannot do is redeem and revolve equities under the safe harbor provision without submitting a request for approval to the FCA, provided the applicable minimum holding period has been completed.

We do not understand the System's comment that an allocated equity with an "express minimum term of 10 years is no more permanent than an allocated equity that is perpetual on its face." In the proposed rule, no term equities were included in CET1. On the contrary, only equities that were both perpetual "on their face" and held for at least 10 years were includible in CET1, and term (limited-life) equities were includible only in tier 2. It is true that, when an institution is placed into receivership, equities held by the institution at that point in time are available to absorb losses of the institution, regardless of whether the equities are perpetual or term and regardless of whether they have been outstanding for 10 years or for 10 days—in a receivership, every equity is as "permanent" as every other equity. We also acknowledge that, like the water level in a bathtub, the capital level of an institution will stay constant if the amount of new capital added is equal to the amount of capital the institution redeems, revolves, or otherwise pays out in cash.[22] But this is not the model of "permanency" embodied in the Basel III framework or the U.S. rule. On an ongoing basis, a reliance on a constant replenishment of new "permanent" capital to replace frequently redeemed or revolved "permanent" capital is inappropriately risky in a weak economy.

The FCA believes that longer revolvement cycles benefit System institutions by enabling them to better capitalize asset growth while also improving the quality and quantity of capital, thus strengthening an institution's financial position. A System institution, like most cooperatives, has limited opportunities to raise capital other than through the direct sale of stock to member-borrowers, the sale of preferred stock to outside investors, and the retention of net income as URE or allocated equities. System associations in particular have adopted the statutory minimum borrower stock requirement of the lesser of $1,000 or 2 percent of the loan, and only one association has issued preferred stock to outside investors. Thus, a System institution is highly dependent on its ability to generate sufficient earnings to repay its creditors, pay cash dividends to outside investors, pay cash patronage to its member-borrowers, and add to its capital base. Cooperative institutions can pay patronage to their member-borrowers in three forms: (1) Cash, which is an immediate return; (2) allocated equities that may be revolved at some future date; or (3) a combination of cash and allocated equities. Allocating equities allows the institution to use this capital for a period of time to benefit the whole cooperative membership, such as for capitalizing growth or improving the financial condition. Many boards choose to revolve allocated equities on an approved cycle, provided that the institution can continue to meet its capital needs. Thus, capital planning assumes greater importance in the capital adequacy assessment for the System institution's long-term survival.

Academic and professional studies[23] conducted of agricultural cooperatives' patronage practices by the U.S. Department of Agriculture (USDA) and others have shown that longer allocated equity revolvement cycles result in stronger balance sheets and a more resilient cooperative. Institutions that maintain shorter revolvement cycles will have greater need to generate proportionally more earnings consistently to maintain the same level of capitalization. The USDA reported, "The largest cooperatives redeemed equity more recently but had a revolving length at 17 years, which was 4 years longer than the smallest cooperatives." Those cooperatives surveyed reported a range of revolvement periods from 7 to 20 years. Some cooperatives also reported retiring equities when a farmer was between 66 years and 72 years of age. Service cooperatives had the shortest revolvement periods at 6 years; and livestock, poultry, and wool cooperatives had revolvement periods of 7 years.[24] This study concluded that cooperatives with shorter revolvement cycles are generally more leveraged and less resilient.[25]

Longer revolvement periods give an institution extra flexibility when earnings are stressed, as well as help maintain stronger capital levels when membership or existing borrowers' operations grow. The FCA strongly believes that System institutions, as financial cooperatives with GSE status, must have redemption and revolvement periods that are sufficiently permanent to maintain strong capital positions in a weak economy.

On the issue of whether System institutions face greater pressure to revolve allocated equities than the pressure on commercial banks to make dividend payments, we disagree with the System. It has long been our position that members can exert more pressure on their institutions because of their dual relationship as borrowers and voting stockholders; by contrast, the voting stockholders of a commercial bank rarely, if ever, have significant business ties with the bank. In other words, unhappy stockholders of a commercial bank do not necessarily or directly lead to a drop in the bank's business. We are particularly concerned about the circumstance of a System institution experiencing low earnings and low growth because the agricultural economy is weak and their borrowers are struggling and most need cash. We acknowledge that the pressure on System institutions to pay cash patronage payments may be comparable to the pressure on commercial banks to pay cash dividends to their stockholders, but we note that the expectation criterion in our proposed and final rule does not apply to cash patronage paid out of URE just as it does not apply to cash dividends paid out of a commercial bank's retained earnings.

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[21] We note, however, that FCA does not anticipate approving early redemptions and revolvements routinely.

[22] This bathtub analogy pertains to the dollar amount of a capital component. Of course, even with a constant dollar amount the capital ratio will change if the amount of risk-based assets changes or if the institution incurs losses.

[23] *See, e.g.*, Robert C. Rathbone and Roger A. Wissman, Equity Redemption and Member Equity Allocation Practices of Agricultural Cooperatives, Agricultural Cooperative Service, U.S. Department of Agriculture (USDA), ACS Research Rep. No. 124 (October 1993); Kimberly Zeuli and Robert Cropp, Cooperatives: Principles and Practices in the 21st Century, University of Wisconsin Center for Cooperatives (2004).

[24] *See* E. Eldon Eversull, Cooperative Equity Redemption, Rural Business—Cooperative Programs, USDA, Research Rep. No. 220 (June 2010) at 6–7.

[25] *See* Rathbone and Wissman at 10–11.

Commenters asserted that they did not experience borrower flight during the years 2007–2013 even given some institutions' reductions in patronage payments. FCA staff has reviewed the patronage payment activities of a number of System associations in the years 2007–2013 leading up to and after the 2008 global financial crisis. Though the financial crisis was deep in many sectors of the U.S. economy, the agricultural economy suffered little impact. Most System institutions had little or no exposure to the "toxic" assets that crippled many financial institutions because of the System's limited lending and investment authorities. In fact, many institutions continued to grow their loan volume. Some impacted institutions did reduce or suspend cash patronage payments and planned redemptions of allocated equities. They did so for a variety of reasons, including to address financial stress and to support increased loan demand. While the experiences of 2007–2013 are useful for analysis, there were no widespread or significant changes in patronage payment practices in the System, particularly redemption or revolvement of allocated equities. Thus, we do not believe these experiences are a strong indicator of what System institutions would experience in a severely weakened agricultural economy.

In the proposed rule, we also intended the minimum holding periods to provide a way for System institutions to comply with the Basel III and U.S. rule's expectation criterion. The expectation criterion, a new concept in Basel III and the U.S. rule, is part of the criteria for all 3 capital components—CET1, AT1, and tier 2 capital. For CET1, the U.S. rule provides that a commercial bank must not "create at issuance of the instrument, through any action or communication, an expectation that it will buy back, cancel, or redeem the instrument, and the instrument [must] not include any term or feature that might give rise to such an expectation." The criteria for AT1 and tier 2 are the same except that the expectation is with respect to exercising a call option on the instrument rather than buying back, redeeming, or canceling it. It is our understanding that this criterion is intended to curb actions like those of some commercial banks that continued to make large share buy-backs and dividend payments during the 2008 global crisis, in order not to send investors a signal of weakness.[26]

There are two noteworthy aspects of the expectation criterion. First, it does not pertain to the intentions—implicit or explicit—of the commercial bank to redeem the instrument, but rather to the expectations created by the bank's behavior—its "actions or communications"—and the focus is on the impact of the bank's actions on others and its communications with others that could lead the bank to redeem stock when such redemption could potentially weaken the bank. The "others" in question could be stockholders, potential investors, the market, or banking analysts and traders.

Second, all the other criteria for CET1 and the other components of capital are based on primarily objective legal rights, legal status, or accounting principles.[27] They cover, for example, perpetual status ("no maturity date"), liquidation priorities and claims, order of impairment, unsecured status without features that legally or economically enhance the seniority of the instrument, redemption only at the discretion of the board and with the regulator's approval, and classification as equity under GAAP. By extension, these criteria mirror the legal rights that a commercial bank's common stockholders have or do not have. The stockholders have no legal right to require the bank to retire or redeem their stock because the stock never matures and because the commercial bank has complete discretion whether to redeem it (with regulatory approval). The expectation criterion does not pertain to legal rights regarding a stockholder's equities; the criterion pertains only to behavior or a pattern of behavior by the commercial bank that leads the stockholder or the market to expect redemption. The FCA has a similar concern regarding the expectations that System institutions may create through their behavior and communications.

The concept of a minimum holding period for System cooperative equities has been a part of FCA's existing core surplus capital regulations that have been in effect since 1997. Under that regulation, an association may include in core surplus allocated equities with an original revolvement period of at least 5 years, as long as such equities are not scheduled by the board or a board practice or expected by the members to be revolved in the next 3 years. The exclusion from core surplus in the last 3 years before revolvement focuses the board on longer-term planning to replace the soon-to-revolve allocated equities and better enables the board to revolve the allocated equities as expected, without reducing the institution's core surplus ratio. The core surplus regulation reflected the Agency's judgment that, first, member expectations of revolvement increase as the revolvement date approaches and, second, minimum revolvement periods make the equities more stable.[28]

The fundamental purpose of allocating equities is to build capital by retaining earnings as opposed to distributing them out as cash. As such, allocated equities need to be sufficiently permanent for the institution to include them in capital. Equities revolved in only a 2- or 3-year period have minimal economic substance or value from a capital perspective, and revolvement periods shorter than 5 years may result in unmanageable borrower expectations and significantly reduced board flexibility to temporarily suspend or defer redemption of allocated equities. Longer revolvement periods ensure these equities are more permanent and stable forms of capital. Since 1997, System institutions have remained adequately capitalized with the existing core surplus rule's 5-year revolvement minimum. However, the agricultural economy and most System institutions have been financially healthy since that time.

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[26] The Basel III document does not specifically discuss the expectation criterion. However, in a discussion of the need for a capital conservation buffer there is an explanation that we believe applies equally to the expectation criterion: "At the onset of the financial crisis, a number of banks continued to make large distributions in the form of dividends, share buy backs and generous compensation payments even though their individual financial condition and the outlook for the sector were deteriorating. Much of this activity was driven by a collective action problem, where reductions in distributions were perceived as sending a signal of weakness. However, these actions made individual banks and the sector as a whole less resilient." Basel III Framework (December 2010, revised July 2011), paragraph 27.

[27] One criterion that is less objective is the requirement that the instrument does not include any term or feature that "creates an incentive to redeem." However, the Federal banking regulatory agencies have previously provided objective standards for commercial banks of the types of terms that create incentives to redeem, such as a dividend step-up term in excess of a specified percentage increase.

[28] The FCA decided not to retain the existing regulation's plan-or-practice standard for allocated equities included in core surplus or the requirement to phase the equities out of CET1 in the 3 years before the end of the holding period. Over the years since we adopted the core surplus rule, a number of institutions have misinterpreted their yearly revolvements of allocated equities as not constituting a plan or practice of revolvement. They have erroneously included allocated equities in core surplus until revolved, rather than phasing them out. We believe eliminating the possibility of misinterpretation is the better course in the final rule, and the longer holding period will ease any concerns about including the equities in the new regulatory capital ratios until the date of revolvement.

As we stated above, we believe a longer minimum holding period for the highest quality capital is more appropriate to ensure adequate capital when the agricultural economy is weak. We believe the holding period for CET1 capital should be longer than the similar 5-year no-call minimum period for lower quality additional tier 1 and tier 2 capital and the minimum term of 5 years for term stock includible in tier 2 capital. The 10-year minimum holding period for CET1 capital in our proposed rule would, in our view, have both tempered member expectations of redemption or revolvement and ensured the stability of capital through the long cycle of the agricultural economy. However, we have considered the System's comments for a shorter minimum holding period for CET1 equities, in light of the rule's other provisions that ensure the retention and conservation of high quality capital, such as the safe harbor provision and FCA prior approval requirements, and the overall higher capital requirements of the rule. We have concluded that a minimum 7-year redemption and revolvement period for CET1 equities will give System institutions added flexibility to manage their capital planning without significantly impacting their resilience. As we have noted, many of the System institutions that revolve allocated equities have already extended, or begun to extend, their revolvement periods to 7 years or longer. The final rule's shorter minimum CET1 holding period, together with our change in the final rule to permit institutions to commit to the minimum holding periods through an annual board resolution, should enable institutions to comply with the new capital requirements with minimal administrative burden.

We have decided not to adopt the System's recommendations of a 3 to 5-year minimum holding period for additional tier 1 capital and elimination of the minimum holding period for tier 2 equities. To do so would be inconsistent with the minimum no-call periods of 5 years for additional tier 1 and tier 2 capital in Basel III and the U.S. rule. Furthermore, elimination of the tier 2 minimum holding period would imprudently permit redemptions and revolvements of equities, such as the member equities issued by some System banks in connection with loan participation programs and the preferred stock issued by some associations to their members, that have been outstanding for as short a period as 1 quarter. In the final rule, we have retained the 5-year minimum holding periods for both additional tier 1 capital and tier 2 capital.

4. Minimum Redemption/Revolvement Cycle for Association Investments in Their Funding Banks

The System Comment Letter objects to the proposed rule's imposition of minimum redemption and revolvement periods on associations' investments in their funding banks. The proposal provided that these investments, which consist of both purchased and allocated equities, have the same minimum redemption and revolvement periods as all other cooperative equities. The System makes the following assertions about the proposed rule's minimum holding period requirement for the association investments in their banks:

- It is challenging, bureaucratic, unworkable, anti-cooperative, costly, and burdensome without any discernible benefit in capital quality or quantity, and it is unnecessary to achieving alignment of System capital regulations with Basel III.
- It is inconsistent with statutory requirements, creates a "first in first out" redemption principle for the investment, impedes a bank's ability to help a struggling association by redeeming or revolving equities, and could create an adverse tax consequence that would necessarily dissipate combined bank-association capital.
- An association's investment in its funding bank "is legally and functionally a permanent capital contribution to the bank and is understood as such by associations," notwithstanding periodic capital equalizations by the System bank (which result in member associations' investments being adjusted, as necessary, to the same specified percentage of its outstanding borrowings from the bank).
- An association's investment in its funding bank "results from the statutorily directed financial relationship." System associations must borrow exclusively from their bank unless they have approval from the bank to borrow from another financial institution. By contrast, an association's borrowers are free to borrow outside of the System.
- The investment requirements imposed on retail borrowers by associations are unlike those imposed by a System bank on its affiliated associations, since associations do not have unilateral authority to increase the requirements. System banks have bylaws that authorize them to call, preserve, and build capital from their associations. Also, a bank's general financing agreement with its affiliated association enables it to increase spreads on outstanding direct loans immediately without association approval.

The capital rule is consistent with statutory requirements. The rule applies the same minimum redemption and revolvement cycles to all cooperative equities except for the statutorily required investment of at least $1,000 or 2 percent of the loan amount, whichever is less. Stock or equities that meet this statutory requirement are exempt from a minimum redemption or revolvement period. We agree with the System that System banks and associations have a relationship defined by the Act that is long term and permanent except for very rare re-affiliations with another System bank or a termination of System status by one or both institutions. However, the statutory minimum required investment is the same for an association to obtain a loan from its affiliated bank as it is for a retail borrower to obtain a loan from an association or from CoBank, ACB, and the exemption from a minimum redemption or revolvement period in our rule applies only to the statutory minimum required investment.

We are not persuaded by the System's position that System banks have authority to call, preserve, and build capital from their associations that their associations lack. Associations have the same statutory and regulatory authority as banks to call, preserve, and build capital; it is the associations that have granted additional capital-building powers to their affiliated banks through bylaw provisions approved by the associations. We appreciate that associations are probably more willing to approve such bylaws because of their financial interdependence with their bank, and association retail members are probably less willing to commit themselves to purchase additional stock in the association. However, the capital-building provisions in a bank's bylaws do not eliminate the need for capital to have a minimum redemption or revolvement period.

The System Comment Letter states that the minimum holding period creates a "first in first out" redemption principle for the investment and impedes a bank's ability to help a struggling association by redeeming or revolving equities. As to the first point, we are not certain what is meant by "first in first out" in the context of a redemption principle, unless it is merely another way to say that associations may have to pay taxes on allocated equities revolved by their banks. The minimum required holding period clearly does not impose a strict requirement that the oldest equities must be redeemed or revolved first. As to the second point, we note that a System bank may redeem or revolve equities prior to the minimum holding period if the bank receives prior approval to do so from the FCA. We believe that the FCA would have a sufficient basis to approve such a request if the bank established that its assistance was necessary or appropriate.

The FCA disagrees with the System's assertion that an association's investment in its affiliated bank "is legally and functionally a permanent capital contribution to the bank and is understood as such by associations." Most System associations do clearly have very long relationships with their affiliated banks, but not all of the equities invested by an association in its affiliated bank are outstanding for lengthy periods. In fact, it appears to us that associations well understand that some of their investments in their affiliated banks are only short-term investments. System banks have discretion under section 4.3A(c)(1)(I) of the Act to redeem and revolve equities anytime, as long as the bank continues to meet the capital adequacy standards established under section 4.3(a) of the Act. By contrast, the CET1 equities issued by commercial banks are more truly permanent, because commercial banks are not permitted to retire such equities without the approval of stockholders owning two thirds of the shares (a statutory requirement) or without the prior approval of their regulator (a requirement of the U.S. rule). Similarly, tier 2 equities issued by commercial banks either are perpetual and require prior approval by their regulator to retire, or are limited-life preferred stock with a minimum term of 5 years (with no prior approval to retire on the maturity date). In our view, third-party investors, relying on an understanding that our capital rules are comparable to Basel III and the U.S. rule, would expect that System institutions' common cooperative equity retirements are subject to substantially the same prior approval requirements as commercial banks' equity retirements.[29] Our proposed rule was somewhat more lenient than the restrictions on commercial banks' equity redemptions in that we did not require banks or associations to obtain stockholder approval before each redemption or revolvement of cooperative equities. We provided additional leniency in a safe harbor provision permitting a certain level of redemptions and revolvements without FCA approval, as long as the equities had been outstanding for at least the minimum holding period. Commercial banks do not have a similar safe harbor for equity retirements, although they do have a safe harbor for cash dividends. We believed, and continue to believe, that our more lenient safe harbor for equities is appropriately comparable to Basel III and the U.S. rule because the safe harbor's broader application to total cash dividend payments, cash patronage payments, and equity redemptions or revolvements is tempered by an overall limit that is more restrictive than commercial banks' safe harbor to pay cash dividends.

For many associations, the greater part of their investments in their affiliated banks is long term in practice. These investments include equities the banks allocated more than 10 years ago, and the banks have stated they do not intend to revolve these allocated equities unless their associations make corresponding allocated equity revolvements to their retail borrowers. Some of these allocated equities are quite stable, due in part to the fact that they are not taxable to associations until they are revolved (System banks' earnings derived from association business are not taxed).[30] As soon as the final rule becomes effective, the banks will be able to include otherwise-eligible allocated equities in CET1 that have already been outstanding at least 7 years (or tier 2 if the allocated equities have been outstanding at least 5 years), and all other allocated equities will be includible in CET1 or tier 2 if the banks adopt a bylaw or annual resolution not to redeem or revolve such equities less than the applicable 7 years or 5 years after issuance or allocation, as long as the equities are otherwise eligible.

However, many associations have investments in their banks that do not have the same stability and "permanence" of the long-held allocated equities. Some of these investments may be the stock purchased by associations to capitalize their direct loans from their banks; other stock is purchased by associations in order to capitalize asset loan participation program pools. Because the capital supporting these loan pools is usually equalized frequently by the bank, banks typically equalize by issuing or redeeming purchased stock because there are no tax consequences when the purchased stock is redeemed. The FCA observes that the practice of tying the investment amount to the loan amount and making frequent equalizations strongly resembles the "compensating balance" method of capitalization that both banks and associations employed in past decades—*i.e.*, the borrower capitalized its loan rather than capitalizing the institution. During the 1980s, many System associations were in such weak financial condition they could not redeem member stock; the also-struggling member-borrowers strongly objected to those associations' not returning their investments when they paid down or paid off their loans, and Congress held a hearing to obtain the testimony of the borrowers. In the Agricultural Credit Act of 1987 (1987 Act), Congress established a statutory capitalization framework that favored capitalization of the institution, not the loan, and disfavored compensating balances, though it did not prohibit them entirely. The FCA believes, as Congress did, that capitalization of the institution rather than the loan provides a stronger and more stable capital base. At the retail level, all System institutions now require borrowers to make only the statutory minimum stock purchase, and in the nearly two decades since the enactment of the 1987 Act System institutions have taken advantage of a healthy agricultural sector to build strong capital positions of high-quality capital that remain in the institutions long term. In addition, one of the four System banks has made the decision not to equalize association investments any longer; instead, the bank pays interest to its associations who hold investments in the bank in excess of the required amount.

We acknowledge that stock equalization at the bank level can be a tool for apportioning the bank's funding and operating costs among its affiliated associations. The FCA supports an equitable apportionment that is based on each association's business with the bank and investment in the bank. However, short-term redemptions and revolvements of equities are not the sole way to ensure that costs are borne equitably by the associations. There are numerous other ways of apportioning the bank's operating costs, such as direct assessments or interest rate adjustments or paying interest to associations whose investments are in excess of bank's required amounts, that take into account the amount of loaned funds or other business with associations and the riskiness of that business. Should a bank prefer to apportion its funding and operating costs in part by equalizing association investments and at the same time hold most of its purchased stock for a term long enough to qualify for CET1 or tier 2 inclusion, it may consider issuing a class of common stock used solely for equalization purposes. The amount a bank might issue could be, for example, an amount equal to the average amount of equities the bank redeems in a given period for purposes of equalization. Such stock, which could be exchanged for a portion of existing outstanding common stock, could be issued and retired at the discretion of the bank and would have no minimum revolvement period, but it would be excluded from CET1 and tier 2 capital. This would by no means eliminate the minimum revolvement period for an association's investment in its affiliated bank, but having a separate class would provide more administrative clarity for the bank, the FCA, and third-party investors.

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[29] It is important to note that, if a System bank includes its affiliated associations' investments in the bank's CET1 capital, those investments will be the common cooperative equities of most interest to a third-party investor in the bank and will likely be a factor, even a significant factor, in such investor's decision whether to invest in a System bank. After all, the bank's URE and CET1 common cooperative equities are the first line of protection for the outstanding third-party equity investments in System banks. If there were no minimum redemption or revolvement period for these cooperative equities, a third-party investor might misunderstand the level of protection these cooperative equities actually provide.

[30] An association's earnings are taxable only when derived from its loans and other business conducted through the parent agricultural credit association or its production credit association subsidiary.

5. Required Capitalization Bylaws Amendments Establishing Minimum Holding Periods

The System Comment Letter objected to the proposed rule's provision that a System institution may include cooperative equities in CET1 and tier 2 capital if the institution has adopted capitalization bylaws establishing minimum required redemption and revolvement periods. The proposed minimum redemption and revolvement periods, or minimum holding periods, were 10 years for inclusion in CET1 capital and 5 years for inclusion in tier 2 capital. Because section 4.3A(b) of the Act requires System institutions to obtain the approval of their members for changes to the bylaws, institutions would have had to exclude cooperative equities from CET1 and tier 2 capital if they had chosen not to seek member approval of the bylaw amendment or if the members had disapproved it.

The System made the following assertions about the proposed capitalization bylaw requirements:

- They are legally tantamount to a re-issuance of the cooperative equities.
- They are fundamentally unworkable, unnecessarily costly, and legally problematic, and they result in a meaningless vote that puts the System institution and its members in a Catch-22 situation.
- The bylaw changes would undermine the institution's ability to function consistent with cooperative principles as expected by the Act. Institutions with modest amounts of cooperative equities may choose to exclude their cooperative equities from regulatory capital than bear the cost, operational burdens, member confusion, and uncertainty of a member vote. If a significant number of institutions make this choice, there could be resulting harm to the overall regulatory capital position of the System.
- Holders of allocated equities that are not voting members may sue the FCA for depriving them of the right to have the institution's board forgo exercising its discretion to revolve the equities during the minimum holding periods.
- There is no basis for a minimum holding period in Basel III.
- A more cost-effective way to ensure there is a legal distinction among equities included in the various components of regulatory capital is to enhance the FCA's capital planning regulation to require boards to adopt binding resolutions regarding the minimum holding periods.

The proposed bylaw requirement to establish a minimum holding period was intended to provide a way for System institutions to comply with the Basel III and U.S. rule's "expectation" criterion. We discuss the expectation criterion under the "Required Minimum Redemption/Revolvement Periods" above.

The FCA's proposed minimum holding periods were also intended to ensure that System institutions equities are substantially comparable to the more truly permanent equities of a commercial bank that can be redeemed only with the prior approval of stockholders and the bank's regulator. Were we to apply identical requirements, System institutions would not be able to redeem or revolve any purchased or allocated equities without FCA approval and stockholder approval. As discussed under the safe harbor section below, the proposed rule would have permitted institutions to make limited redemptions and revolvements without regulator and stockholder approval. We believe that a minimum holding period lowers expectations of redemption or revolvement, and the bylaw requirement ensures both institution compliance and member buy-in regarding the minimum periods. A bylaw requirement would have explicitly established that a System institution's board had firmly committed, with its members' support, to limit its discretion under section 4.3A of the Act to redeem or revolve equities, in exchange for being able to include the equities in tier 1 and tier 2 capital, and that the institution's members understood and supported this limit on the board's discretion. However, we have considered the System's comments on the bylaw approval process and are persuaded that requiring an institution's board to adopt a redemption and revolvement resolution that it must re-affirm in its capital plan each year would be sufficient to ensure compliance with the rule's minimum holding periods. As described below in the section-by-section discussion, we have revised the capital planning regulation in § 615.5200 to require the institution's board to establish minimum redemption and revolvement periods for specifically identified equities included in tier 1 and tier 2 capital. Any change to the minimum periods will require FCA approval. The board will also be required to re-affirm annually its intention to comply with the capital rule's minimum holding periods. We note that this annual re-affirmation is not an annual opportunity for the board to change its mind about the redemption or revolvement periods of specified equities. In addition, for institutions that prefer a capitalization bylaw to an annual board resolution, we have retained the proposed capitalization bylaw provision as another method of compliance with the minimum holding periods.

6. Higher Tier 1 Leverage Ratio and Minimum URE and URE Equivalents Requirement

The System Comment Letter objected to the proposed 5 percent minimum tier 1 leverage ratio and also on the requirement that at least 1.5 percent of the tier 1 capital must consist of URE and URE equivalents. The System's objections are as follows:

- A 5-percent tier 1 leverage ratio requirement is excessive, is unsupported, is inconsistent with the 4 percent tier 1 leverage ratio of Basel III and the U.S rule, would create an un-level playing field that gives an advantage to commercial banks in the capitalization of loans to farmers, and may raise questions and suspicion that the System is fundamentally riskier compared to other lending institutions.
- Such an inference does irreparable harm to the System and its mission achievement, given the lack of any quantifiable support for the higher minimum. The FCA has not provided "reasonable facts or data analysis" to support a higher minimum leverage requirement that could reduce institution lending capacity by over 20 percent during stressful periods. The FCA's justification is insufficient and unsupported by loss experience, making this proposed requirement arbitrary and capricious.

- The Basel III framework's minimum leverage ratio requirement, a measurement that was not required by Basel I or Basel II, was imposed in response to the “drying up” of liquidity during the financial crisis, which revealed inter-connections and interdependences between financial institutions and resulted in pressure on commercial banks to retire lower quality tier 1 capital instruments (hybrid instruments) when they were most needed to absorb losses. Stress-testing and economic modeling by System institutions show the System has enough loss-absorbing capital to withstand a severe adverse economic event while continuing to provide a steady flow of credit to agriculture.
- The interconnectedness of System institutions is an inherent part of the structure of the System and, despite its interconnectedness and its status as a monoline lender, the System remained “essentially unstressed” during the financial crisis.
- The proposed minimum leverage ratio is inappropriate for wholesale System banks and appears to create economic incentives for shifting ownership of loans from associations to System banks. The agency “appears not to have considered the two-tiered capitalization that exists within the System” that results in the System as a whole effectively holding minimum risk-based capital for association retail loans totaling 120 percent of the amount required for commercial banks. The risk-based capital requirements are more than adequate to protect against not only credit risk but also liquidity risk, operational risk, and other risks.
- There is no empirical evidence that the System's risks are more significant than the systemic risks that caused the financial crisis. FCA should support its higher minimum leverage ratio by conducting a study that demonstrates and quantifies that the proposed significant deviation from Basel III is justified by facts. After such a study, if the FCA remains focused on imposing a higher leverage ratio, the agency should consider a 4 percent minimum leverage ratio with an additional 1 percent leverage ratio buffer composed of tier 1 (not CET1) capital and pro-rated across the payout categories. Overall, a capital conservation buffer approach would support the objective of the proposed higher leverage ratio without unduly penalizing those System banks primarily engaged in wholesale lending to associations.
- The proposed 1.5 percent minimum URE requirement “calls into question the cooperative structure of the System” and “declares that URE is higher quality capital than CET1.” This “‘super’ or ‘superior’ CET1 subclass is an unmistakable message to the marketplace that the System's CET1 does not match up with CET1 of commercial banks” and reduces comparability and transparency.
- Implementation of the URE requirement results in a minimum 3 percent of URE (1.5 percent by the bank and 1.5 percent by the association) required to be held against each dollar of loans made by associations to member-borrowers. This violates the cooperative principle that members bear the risk and reward of their institution.
- The 1.5 percent minimum URE requirement, similar to a required component of the core surplus ratio in the FCA's existing regulations, should not be in the new capital framework. The FCA's reason for the existing URE requirement in core surplus was that higher URE levels cushioned member stock from impairment, thus minimizing the prospect of members seeking protection of their equities from Congress. Congress has already made it clear that members are at risk and will suffer the losses of the cooperative. Congress's action with respect to Fannie Mae and Freddie Mac emphasizes its resolve to allow significant shareholder losses regardless of personal impact.

The FCA disagrees with many of the System's comments and assertions. We do not believe a 5 percent minimum standard would create an “unlevel” playing field for the System that would give any appreciable advantage to commercial banks or raise suspicions that the System is fundamentally riskier than commercial banks. At the retail association level, there are so many differences between associations and commercial banks with respect to stable sources of funding, lending authorities, lending territories, tax status, and governance that we believe a higher minimum leverage ratio would not tilt the playing field. A higher leverage ratio requirement enhances the System's ability to achieve its mission by ensuring that System institutions have sufficient capital to achieve its mission, during good times as well as during periods of financial stress. More specifically, a higher leverage requirement will ensure that System institutions have sufficient amounts of capital at the height of the credit cycle so that they can continue to lend during a downturn, and thus, fulfill their mission. During a downturn, System borrowers need access to credit to ensure the continuation of their operations, and System institutions must ensure that they can continue to be a reliable source of credit to these borrowers. Moreover, we do not believe that a higher minimum leverage ratio for associations will raise suspicions in the capital markets. To our knowledge, individual association capital is not the focus of the capital markets, as we are aware of only one association that has raised equity capital from outside the System.[31]

At the System bank level, the banks are able to issue Systemwide debt as a single entity because they are jointly and severally liable on the debt. The System's combined assets were approximately $300 billion as of December 31, 2015. By contrast, the vast majority of commercial banks subject to the 4 percent tier 1 leverage ratio requirement are considerably smaller in size than the combined size of the System.[32] Commercial banks subject to the “advanced approaches” Basel framework (*i.e.*, banks with more than $250 billion in total consolidated assets) are also subject to the supplementary leverage ratio (SLR),[33] which has a minimum requirement of 3 percent. The SLR, which takes into account both on- and off-balance sheet exposures, could result in a higher requirement than the 4-percent tier 1 leverage ratio requirement, which includes only on-balance sheet exposures. Commercial banks with more than $700 billion in total consolidated assets are subject to a 2-percent leverage buffer in addition to the 3-percent SLR (totaling 5 percent).[34] System banks, by contrast, are not constrained by a supplementary leverage ratio, yet they are able to obtain funding at low rates comparable to the rates obtained by the largest U.S. banks. We would anticipate that the capital markets and outside investors would welcome a higher leverage ratio requirement that ensures higher capital levels to absorb losses and protect outside investors, rather than “raise suspicion that the System is fundamentally riskier compared to other lending institutions.”

The FCA disagrees that the Basel III framework imposed a minimum leverage ratio requirement in response to the “drying up” of commercial bank liquidity during the financial crisis. The 2008 financial crisis did begin with a severe liquidity crisis, but liquidity concerns were addressed primarily by Basel III's liquidity coverage ratio and the net stable funding ratio. The FCA updated the liquidity regulation in 2013 to incorporate the liquidity coverage principles of Basel III, as appropriate to the System.[35] We also plan to study Basel III's liquidity coverage ratio and the net stable funding ratio to determine what, if any, application they should have to the System.[36] The leverage ratio requirements in the Basel III capital framework were adopted to avoid future repetition of periods of excessive growth, resulting in excessive leveraging of capital, that are followed by a sharp downturn in the economy that causes very large losses.

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[31] In fact, market investors in System banks may prefer high capital ratios at associations on the ground that the associations' higher capital levels strengthen the banks and decrease the chances that a bank would need to provide financial assistance to an association.

[32] The System reported combined assets of $303 billion including the restricted investment in the Farm Credit Insurance Fund, at December 31, 2015. See 2015 Annual Information Statement of the Farm Credit System issued March 7, 2016.

[33] 78 FR 62018 (October 11, 2013).

[34] 79 FR 57725 (September 26, 2014).

[35] *See* the amendments to § 615.5134 in 78 FR 23438 (April 18, 2013).

[36] *See* FCA's Regulatory Projects Plan at *http://www.fca.gov/Download/RegProjPlanSpring2016.pdf.*

We agree with the System's statement that the System remained "essentially unstressed" during the financial crisis despite its status as a monoline lender and the interconnectedness of System institutions. In our view, while the cyclical nature of the agricultural economy can increase agricultural lending risk overall, the agricultural economy happened to be at a very strong point in the cycle during the financial crisis. The System's low level of agriculture loan losses during the financial crisis, together with minimal exposure to troubled residential mortgages due to legal restrictions on the loans and investments System institutions can make, enabled the System to weather the financial crisis relatively unstressed.

Contrary to another System comment, the FCA did carefully consider the two-tiered structure of the System—*i.e.*, the banks' wholesale funding of associations' retail loans—when proposing the tier 1 and tier 2 risk-based capital requirements. In fact, since the agency first proposed and adopted risk-based capital regulations in 1988, System institutions have consistently objected to the 20-percent risk weight applied to a bank's direct loan to an affiliated association and have asserted that the capital held by an association against its retail loans results in a zero risk of loss to the bank on the direct loan. Our position has been, and continues to be, that the direct loan represents a relatively small but separate and distinct credit risk to the bank, and the 20-percent risk-weight is appropriate, as well as consistent with the risk weightings for GSE securities and debt. We do not agree that the small amount of risk-based capital held by the System bank against credit risk on its direct loans, as well as the relatively small amounts of capital held against credit risks on most of its other exposures, is an adequate substitute for a tier 1 leverage ratio. As explained below, we believe that both System banks and associations need high quality minimum leverage ratios.

The FCA disagrees with the comment that a leverage ratio is inappropriate for wholesale banks. A leverage ratio can be more challenging for a wholesale System bank, since the majority of its assets are risk-weighted at 20 percent, while those of associations are risk weighted at 100 percent. However, as discussed elsewhere in this preamble, the two-tiered capitalization requirement recognizes the separate risks in the System structure and risks that are present to each party. The capital an association holds against loans to its borrowers offsets the general risk from those loan exposures, while the bank must hold capital to offset the general risk from its loan exposure to its affiliated associations. If banks did not hold capital against these exposures, the risk in loans to association borrowers would be present to both the bank and association but only capitalized by the association. In addition, the banks and associations have levels of operational risk, such as legal risk and management risk, that do not correlate with the level of credit risk. The Basel III framework and the U.S. rule do not exempt wholesale banks from their leverage ratio requirements, and we are not convinced that we should do so. As for the System's comment that our leverage requirements appear to create an economic incentive for shifting ownership of retail loans to the System banks, banks and associations are already doing this. If a bank agrees with its associations to buy their retail loans, that is a business decision for the institutions that is probably made for business reasons in addition to regulatory capital compliance.

We also disagree with the assertion that the minimum URE requirement is anti-cooperative. The requirement ensures at least a minimum level of URE and URE equivalents, and an institution may choose to meet this requirement with URE equivalents plus current year retained earnings. URE equivalents are nonqualified allocated equities that are not revolved and generally not subject to offset against a loan in default (without prior FCA approval). In any case, the characterization of URE as anti-cooperative is inapt for most cooperatively organized financial institutions, such as mutual savings associations. Such institutions have regulatory capital that consists entirely of unallocated retained earnings. We note that the National Credit Union Administration (NCUA) issued a final rule in 2010 for corporate credit unions (which are also cooperative institutions),[37] which requires that their leverage ratio must consist of at least 2 percent of retained earnings to be adequately capitalized.[38] The NCUA's logic and belief is that a corporate credit union's capital must consist of retained earnings, which is the only form of corporate capital, that when depleted, does not result in losses that flow downstream to natural person credit unions. Without some retained earnings, the corporate credit unions would be a continued source of instability to the credit union system as whole. FCA believes this also applies to System institutions, as discussed throughout this preamble.

We agree that Congress, in the provisions of the 1987 Act, sent a message that member stock was at risk and that members would be subject to their institutions' losses.[39] We also observe that Congress protected member stock outstanding at the time from loss. We believe this "helping hand" in a time of need illustrates Congress's confirmation of the importance to the entire U.S. economy of a strong agricultural sector and also of Congress's recognition that strength in the agricultural sector is inextricably linked to the personal financial stability of its farmers and ranchers. By contrast, in the case of the 2008 conservatorships of Fannie Mae and Freddie Mac, the actions of Congress and the Federal government ensured the continuing function of the secondary mortgage market for the benefit of U.S. homeowners but did not provide similar protection for the personal financial stability of the stockholders of the housing GSEs.

The 1987 Act also sent a strong message to the System not to expect Congress to provide financial assistance in the event of significant losses in the future.[40] We believe this reinforced the FCA's mandate under section 4.3(a) of the Act to "cause System institutions to achieve and maintain adequate capital" that will have the added benefit of protecting the institutions' members from impairment of their equities. In our view, a healthy portion of URE and nonrevolving URE equivalents reduces the possibility that those equities will be impaired during times of stress in the agricultural sector. URE protects against the risk that exists between System banks and associations: It protects association members against association losses, associations against bank losses, and the System against financial contagion. A minimum level of URE is needed to cushion third-party and common cooperative equities and would greatly limit the potential losses to holders of these instruments. For example, if a funding bank had a loss and there was no URE at the bank to absorb the loss, the association's stock investment in the bank would be the first line of capital to absorb the loss. The association could be required to recapitalize the bank and the bank could also increase its spread it charges on the direct note to generate additional earnings to replenish its capital. If the funding bank did not have URE as the first line of defense in its capital to protect the association's investment, losses at the bank would negatively impact the association's earnings, which could further impact association patronage distributions to member-borrowers. This same argument is applicable to a member-borrower's investment in an association. Whether or not the capital markets and prospective investors conclude that URE and URE equivalents are a "superior subclass" of CET1 is, in our view, probably not going to confuse investors or make a material difference to them. What is important and clear to investors is that all of the CET1 elements will protect all of the third-party equities and sub debt issued by a System bank or association.

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[37] 75 FR 64789 (October 20, 2010).

[38] To our knowledge, all of the retained earnings of credit unions are unallocated. The "corporate credit unions" discussed above are cooperatives owned by natural person credit unions and provide liquidity and other services to their member owners.

[39] We emphasize that, before the 1987 Act, member stock was at risk, but most institutions treated it like a compensating balance, and many associations failed to advise their retail borrowers that the stock was at risk. The 1987 Act added a "guarantee" that existing outstanding member stock that was issued prior to October 1988 would be redeemed at par or face value upon repayment of the member's loan.

[40] Part of that message was embodied in the creation of the Farm Credit System Insurance Corporation (FCSIC) and the Insurance Fund, but the Insurance Fund primarily protects System-wide debtholders.

The System also asserted that if FCA is determined to require a minimum URE standard, then it should be based on risk-adjusted assets, which is consistent with FCA's current regulatory requirements. The URE requirement would not undermine the System's ability to manage its capital sources as this requirement is only applicable to the tier 1 leverage ratio. We also believe that the 1.5-percent URE requirement should be based on total assets rather than risk-adjusted assets, as System commenters recommended. We believe this requirement is simple, transparent, easy to understand, and reflects the true underlying risk inherent in each System institution. A URE minimum based on risk-adjusted assets benefits institutions with favorable risk weights, and this may not be sufficient to protect System borrowers against a systemic event. We note that over half of the System's capital consists of URE and URE equivalents, with all System institutions easily meeting the required 1.5 percent.

As to the System's assertion that too much URE undermines the user-control and user-ownership principles, we disagree. Section 1.1(b) of the Act encourages farmer and rancher-borrowers to participate in the management, control, and ownership of a System institution, and the URE requirement does not undermine this section of the Act. All farmer and rancher-borrowers are allowed one vote, regardless of the amount of their investment in their System association. Moreover, the URE requirement can be fully met with nonqualified allocated surplus and stock, which supports the cooperative principle of user-ownership.

The System has asserted that the FCA has not provided reasonable facts, data analysis of loss experience, or empirical evidence to justify a 5-percent minimum leverage ratio. Much of the data the Basel Committee studied in its formulation of the Basel III framework was from the recent financial crisis. For similar data on the System, the FCA would have to go back to the 1980s, when the weakened agricultural economy in combination with the System's interest-rate model at the time resulted in borrower flight, significant losses of System capital, and eventually a Federal bailout. The scarcity and age of most of the relevant data make it of only limited use to us in formulating a leverage ratio, and both the System and financial world have changed radically since the 1980s. Another approach would be to wait until after the next crisis in the System, study the data, and formulate a new leverage ratio based on lessons learned. However, leaving the tier 1 leverage ratio out of our tier 1/tier 2 capital framework would make our capital rule far less comparable to Basel III and the U.S. rule than would a higher minimum leverage ratio.

Because of the scarcity of useful data at this time, the FCA has decided not to do a study to "demonstrate and quantify" that a 5-percent minimum leverage ratio is appropriate. However, the FCA does find considerable merit in the System's suggestion to replace the 5 percent minimum leverage ratio with a 4-percent minimum leverage ratio and a 1 percent leverage buffer, and we have revised the final rule to incorporate this suggestion. A 4-percent minimum tier 1 leverage ratio with a 1-percent tier 1 buffer will give additional flexibility to System institutions to make capital distributions and discretionary bonus payments (albeit on a more restricted basis), will appropriately address the System's concerns about a higher minimum leverage ratio giving an unwarranted negative impression about System operations to the capital markets, and will assure the FCA that System institutions will continue to hold healthy amounts of capital against all institution risks.

7. Safe Harbor Requirement

The System Comment Letter states the System "respect[s] in principle" the need for restrictions on capital distributions but objects to the proposed safe harbor as follows:

- Limiting capital distributions to the past year's net retained income and not allowing for any reductions in CET1 from the prior year-end makes management of regulatory capital "exceedingly challenging and inflexible" and provides no reasonable room to do so without seeking FCA prior approval.
- The safe harbor is far more restrictive than foreign cooperative bank regulators' safe harbor, allowing a reduction in CET1 of up to 2 percent without prior approval, and U.S. law that allows capital distributions equal to current year's earnings plus the retained net income for the prior 2 years.
- The 30-day approval process is burdensome and unworkable and should be streamlined for institutions with high FIRS ratings, with FCA granting approvals in as short a time as one day.

In practice, System institutions rarely pay dividends on preferred stock, make cash patronage payments, redeem or revolve equities that exceed their prior 12 months' net earnings. Associations generally pay out less than 50 percent of earnings, and only 5 System associations had payout ratios that were over 60 percent of their earnings in 2014. The 30-day approval is in effect a notification to the FCA of the intended payment, and an institution may make the payment after 30 days if the FCA has not disapproved it or not acted on the request. We expect boards to give significant thought to capital distribution decisions and how they impact overall capitalization of their institution, especially regarding a cash payment that exceeds net income over the past 12 months. The cash payments are generally made at very predictable intervals during the year (unlike, for example, funding requests), and we have not identified any situations where institutions are likely to need to make unplanned, significant capital distributions. Therefore, the FCA does not believe the safe harbor rule will be exceedingly challenging and unworkable for System institutions.

Our rule's safe harbor is different from the "advance permission" allowed by the European Bank Authority (EBA) as it is described in the System Comment Letter. The EBA has issued regulatory technical standards (RTSs) and guidelines that are binding on its member states, but it is up to the member states to promulgate regulations for their own countries. The RTS cited in the System Comment Letter regarding redemptions, reductions, and repurchases by European cooperative financial institutions permits member states to give advance permission for redemption of predetermined amounts for a period of up to 1 year; however, the predetermined amount "shall not exceed 2% of [CET1] capital."[41] We have several observations. First, it is unclear to us whether this advance permission has the same effect as our safe harbor, because the EBA has responded in its online Q&A Rulebook that an institution must deduct from capital the predetermined amount in question as soon as its regulator grants authority to make the payment.[42] Under our safe harbor, a System institution does not have to deduct a cash payment until declared or approved by its board. Second, we interpret the RTS merely to put a cap of 2 percent on the predetermined amount, and we do not know whether any member states have adopted the advance permission provision or, if they have, whether they have adopted a cap of 2 percent or a lower amount. Third, our safe harbor has more flexibility than the RTS in some ways. The advance permission caps all cash payments at an amount that equals 2 percent of CET1, regardless of whether CET1 declines. Our safe harbor, by contrast, does not restrict the amount of tier 2 cooperative equities that a System institution may revolve because revolvement of tier 2 equities does not reduce the dollar amount of CET1 capital.[43] Furthermore, it is theoretically possible under our safe harbor for a System institution's CET1 capital ratio to decline more than 2 percent—due to a previous cash payout or simply because the institution's risk-based assets have increased—and the institution will still be able to make a cash payout as long as the dollar amount of CET1 does not decline below the dollar amount 12 months prior to the payout.

We are aware that our safe harbor is more restrictive than the safe harbor amounts for commercial banks, in terms of cash payments for dividends, but we believe there are important reasons for the difference. First, U.S. national banks under 12 U.S.C. 60 have authority to pay cash dividends without prior regulatory approval in an amount up to current year's net income and the retained net income of the 2 previous years, and their regulator is not authorized to reduce that limit. With respect to cooperative System institutions, a lower limit is more prudent. We note also that our safe harbor is more permissive in several ways. It includes equity redemptions and revolvements, whereas Basel III and the U.S. rule require commercial banks to obtain prior regulatory approval before making stock redemptions. In addition, 12 U.S.C. 59 requires national banks to obtain the approval of shareholders owning two thirds of the shares of each affected class as well as OCC approval.

The System Comment Letter requested that institutions be able to redeem and revolve equities owned by the estate of a deceased former borrower and equities related to a defaulted or restructured loan without restriction. As discussed below in the section-by-section discussion, we have decided to exempt some of these redemptions and revolvements, as well as redemptions and revolvements ordered by a court, from the minimum holding period requirements in the safe harbor. This means that such cash redemptions and revolvements remain subject to the safe harbor on the amount of cash payments the institution can make.

8. Risk Weighting of Electric Cooperative Assets

By FCA Bookletter BL–053, dated February 27, 2007, the FCA permitted System institutions to assign a lower risk weight than would otherwise apply to certain electrical cooperative assets, based on the unique characteristics and lower risk profile of this industry segment.[44] Exposures to certain electrical cooperative assets that satisfy specified conditions receive a 50-percent rather than a 100-percent risk weight. Furthermore, exposures to these assets receive a 20-percent risk weight if the assets have a AAA or AA credit rating.

We did not propose this favorable risk weighting for these exposures in this rule, but we sought comment as to whether we should retain this risk weighting. We received comments from approximately 65 electric cooperatives, in the System Comment Letter, and from several individual System institutions, all requesting that we retain a favorable risk weighting for these exposures.

The electric cooperatives specifically urged us to retain the 50-percent risk weighting, stating that the rationale in BL–053 regarding the unique characteristics and lower risk profile of the industry segment remains valid today. These commenters also asserted that raising the risk weighting would drive up their borrowing costs and would ultimately hurt rural electric rate payers.

The System Comment Letter and the individual System institutions urged us to retain both the 50-percent and the 20-percent risk weighting. They stated that the bookletter's rationale for these risk weights remains true today. In addition, they stated that the key institutions that provide financing to this segment, other than CoBank, ACB, and the U.S. Government, are not regulated, and they asserted that it is critical that FCA's capital rules not affect the System's ability to compete and collaborate with other lenders in meeting the financing needs of rural electric cooperatives.

These commenters also stated, without support, that a higher risk weight for these exposures would impede the ability of CoBank, ACB to competitively meet its mission to serve this industry and would therefore also harm rural residents and businesses. In addition, several institutions stated that their ability to purchase participations from CoBank, ACB allows them to diversify their own portfolios and therefore reduces their own credit risk.

We do not include this lower risk weight for exposures to electric cooperative assets in this final rule. However, FCA Bookletter BL–053 remains in effect. We continue to evaluate the comments we have received and anticipate that we will issue further guidance on the capital treatment of these exposures in the future. As under existing FCA Bookletter BL–053, this treatment would be authorized under our reservation of authority.

9. Risk Weighting of High Volatility Commercial Real Estate Exposures

Because of the increased risk in these activities when compared to other System lending, we proposed to assign a 150-percent risk weight to HVCRE exposures, unless those exposures satisfied one or more of four specified exemptions. As in the U.S. rule, our proposed rule would have defined an HVCRE exposure as a credit facility that, prior to conversion to permanent financing, finances or has financed the acquisition, development, or construction of real property. Also as in the U.S. rule, four types of financing would have been exempted from this definition.

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[41] *See https://www.eba.europa.eu/documents/10180/359901/EBA-RTS-2013-01-draft-RTS-on-Own-Funds-Part-1.pdf/d1217588-ff05-4063-8d6f-5d7c81f2cc64.*

[42] *See http://www.eba.europa.eu/single-rule-book-qa/-/qna/view/publicId/2014_1352.*

[43] We note that the safe harbor includes redemptions and revolvements of cooperative equities only, not third-party equities.

[44] The FCA authorized this risk weight under our regulatory reservation of authority in § 615.5210(f), which permits us to determine the appropriate risk weight for an asset if the risk weight specified in the regulation does not appropriately reflect the asset's level of risk. This provision will be replaced by § 628.1(d)(3) in the new rule.

The System Comment Letter and several individual System banks and associations expressed concern about some of the proposed HVCRE provisions and requested clarification of a number of issues. These commenters raised important questions that we wish to consider and analyze further. Accordingly, we are not finalizing the provisions governing HVCRE exposures at this time. We expect that we will engage in additional rulemaking or issue guidance on HVCRE exposures in the future.

As we consider these issues, we will be guided by the objectives of this rule, which include, as stated above:

- Modernizing capital requirements while ensuring that institutions continue to hold enough regulatory capital to fulfill their mission as a GSE; and
- Ensuring that the System's capital requirements are comparable to the Basel III framework and the standardized approach the Federal banking regulatory agencies have adopted, while also ensuring that the rules take into account the cooperative structure and the organization of the System.

We note that new § 628.1(d)(3), like existing § 615.5210(f), reserves the FCA's authority to require a System institution to assign a different risk weight to an exposure than the regulation otherwise provides if that risk weight is not commensurate with the risk associated with the exposure. Accordingly, under both the existing rule and the new rule, FCA has the authority, where warranted, to assign a higher risk weight to an exposure that satisfies the characteristics of HVCRE exposures, even without a specific regulatory HVCRE risk weight.

For example, FCA has recently approved requests by System institutions to purchase and hold investments pursuant to § 615.5140(e).[45] As part of our approval of those investments, the FCA has used our regulatory reservation of authority to impose a 150-percent risk weight on the investments, including during the time the facilities being financed are in the construction phase. The FCA expects to continue to exercise its reservation of authority as warranted to assign risk weights that are commensurate with the risks in exposures.

10. Unused Commitments To Fund Direct Loans

We proposed to impose risk weight and credit conversion factor (CCF) requirements on the unused commitments from System banks to associations to fund their direct loans.[46] The agreement by a System bank to fund a direct loan satisfies the rule's definition of commitment, which is "any legally binding agreement that obligates a System institution to extend credit or to purchase assets."[47] Moreover, as discussed in the preamble to the proposed rule, we believe these commitments carry risk that warrants the holding of capital against them.

We received comments opposing this proposal in the System Comment Letter and from several individual System institutions, including both banks and associations. Their comments, and our responses, are set forth below.

The commenters stated that requiring banks to hold capital against these commitments results in the double counting of commitment exposures, because associations hold capital against their loans and commitments to retail borrowers, and the associations' funds come from their loans from the bank.

As we explained in the preamble to our proposed rule, although this treatment may be viewed as the double counting of exposures, it is consistent with the way we treat loan exposures; we require a System bank to hold capital against the outstanding balance of its loan to an association, and we also require an association to hold capital against its loans to borrowers (even though the association's loaned funds come from its loan with the System bank).

As with loan exposures, there are separate risks involved in System bank commitment exposures to associations and association commitment exposures to retail borrowers, and this treatment recognizes those separate risks. The capital an association holds against a commitment to its borrower offsets the general risk from that loan commitment, while the System bank must hold capital to offset the general risk from its loan commitment to its affiliated association. Even if the association is adequately capitalized with respect to its commitments, some risk to the System bank remains.[48]

The commenters also contended that this capital treatment undermines well-established capital adequacy management disciplines used within the System because it confuses the concepts of capital for growth purposes and capital needed to fund existing commitments; System banks already build additional capital in anticipation of loan growth, including commitments.

While System banks may currently capitalize their commitments to associations as part of the capital they hold for loan growth purposes, capitalization of these commitments has not been pursuant to FCA regulations. This new regulation requires System banks to hold capital specifically for the purpose of capitalizing their commitments to associations. Beyond that amount, banks should hold sufficient additional capital for loan growth purposes. If, as the commenters assert, banks already capitalize their commitments to associations, then they should not need to hold additional capital under the new rule.

The commenters also stated that commitments from System banks to associations are different from and lower risk than other commitments, such as commitments from System associations to retail borrowers, because of System interdependencies and features of the GFA.

One difference, according to the commenters, is that in contrast to a typical lending relationship, such as that between an association and a retail borrower, in which the note establishes the definitive amount of the obligation, the GFA in a bank-association direct loan is open ended, providing for continued funding with no limit on the amount, as long as all terms and conditions of the GFA are met. Accordingly, there is no specific amount of unused commitment from the bank to the association in the traditional sense. This arrangement evolved from the symbiotic nature of the federated cooperative relationship between banks and associations, and it allows for growth of the associations without the necessity for administrative burdens such as numerous amendments to promissory notes and loan documents.

In response to this comment, we note that § 614.4125(d) requires the GFA or promissory note to establish a maximum credit limit determined by objective standards as established by the System bank. Prior to this rulemaking, FCA had never opined on whether this provision requires a specific dollar amount for the maximum credit limit in the GFA or promissory note. By proposing to determine the exposure amount of the commitment by reference to the maximum credit limit, however, FCA made clear that the regulation requires the maximum credit limit to be a specific dollar amount. We believe that this requirement ensures that banks engage in appropriate planning so that they will always be able to fund these commitments.

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[45] Section 615.5140(e) authorizes System institutions to purchase and hold investments as approved by the FCA. The FCA approves such investments on a case by case basis.

[46] Such a commitment is not unconditionally cancelable by the System bank. Under the GFA that governs the commitment, a System bank must continue to fund the commitment as long as the association or OFI satisfies specified conditions.

[47] Section 628.2.

[48] As an illustration of why the System bank faces risk that is separate from the association's risk from its borrowers, an association could use money it borrows from the bank not only to establish and expand commitments and loans to borrowers but also to invest, hedge risk, replace equipment, or fund new facilities and services.

We do not believe that this requirement would lead to numerous amendments to the GFA or promissory note. System banks and associations should establish a reasonable, specific dollar amount by considering the association's existing retail loans, commitments, other credit needs, and expected growth over the term of the commitment. If institutions engage in sound planning, this amount should rarely need to be changed within that term. We note that some System banks already have established a specific dollar amount for their maximum credit limits and have not identified any difficulties in doing so.

Another difference, according to the commenters, is that the GFA protects the System bank in a way that associations are not protected with respect to their retail borrowers. The GFA is typically secured by all of an association's assets, with discounts that cause the bank's collateral position to exceed the borrowing base.

In addition, according to the commenters, the GFA contains a number of covenants that provide safeguards that make it unnecessary for the bank to hold capital to support its commitments to fund direct loans. These covenants include a liquidity covenant that effectively limits the association's ability to borrow in excess of a percentage below the actual borrowing base without the bank's approval, which serves as an equity buffer to absorb losses in the event of credit adversity.

These covenants also include a requirement to maintain a minimum return on assets ratio of one percent and the requirement to submit a corrective action plan if an association's adverse assets to risk funds ratio exceeds 50 percent and to maintain a ratio of adversely classified assets to risk funds of less than 75 percent. In the event of default of either of these ratios, the bank has the right to take a wide variety of actions that could control its risk. The GFA also provides controls for early identification of potential events of default for associations with credit issues.

We are not persuaded that the GFA covenants and other provisions eliminate the need for System banks to hold capital against their commitments to fund direct loans. While these provisions do provide some protection to System banks, loan documents governing other commitments, such as the retail commitments of associations, often contain provisions that provide similar protections.[49] Nevertheless, those commitments require the holding of capital. Even with these protections, the commitments still carry risk.

Moreover, we believe the relationship between System banks and affiliated associations carries risk that isn't present in most other lending relationships, such as that between associations and their retail borrowers. Although the GFA permits a bank to terminate an association's loan or to refuse to make additional disbursements in the event of default, an association can borrow only from its affiliated bank.[50] We believe a bank would be reluctant to terminate an association's loan or refuse to make additional disbursements, even if the association is in default, because that would leave the association with insufficient funds to carry on its operations. Accordingly, a bank has an incentive to continue to fund an affiliated association, even if that association is in default. This risk factor is not present in most other lending relationships.

Nevertheless, because of the nature of the relationship between a System bank and its associations, we believe the risk in the commitment to fund the direct loan does not increase with the term of the commitment, as it does with other commitments. Accordingly, the final rule assigns a 20-percent CCF to all unused commitments to fund direct loans, regardless of the terms of the commitments.[51] We are not assigning a 50-percent CCF to such commitments with original maturities greater than 14 months, as we proposed. We believe this difference in capital treatment for unused commitments on System direct loans is warranted because of the nature of the System bank-association relationship, which has no equivalent outside of the System.

II. Minimum Regulatory Capital Ratios, Additional Capital Requirements, and Overall Capital Adequacy

A. Minimum Risk-Based Capital Ratios and Other Regulatory Capital Provisions

The FCA proposed to adopt the following minimum capital ratios: (1) A common equity tier 1 (CET1) capital ratio of 4.5 percent; (2) a tier 1 capital ratio of 6 percent; (3) a total capital ratio of 8 percent; and (4) a tier 1 capital leverage ratio of 5 percent, of which at least 1.5 percent must be composed of URE and URE equivalents. Tier 1 capital equals the sum of CET1 and AT1 capital. Total capital consists of CET1, AT1, and tier 2 capital. We proposed to rescind the existing core surplus, total surplus, and net collateral regulations and proposed amendments to the permanent capital requirements. We did not propose to rescind the permanent capital regulations because the permanent capital ratio is required by the Farm Credit Act.

In addition, we proposed a capital conservation buffer in excess of the new risk-based capital requirements that imposed limitations on capital distributions and certain discretionary bonuses, as described in section II.C below. The capital conservation buffer is not considered to be a minimum capital ratio requirement.

In the final rule, we are adopting the new risk-based minimum ratios and the capital conservation buffer as proposed. However, we revised the minimum tier 1 leverage ratio requirement to 4 percent and added a 1-percent leverage buffer requirement as described in section II.B below.

Consistent with the FCA's authority under the Farm Credit Act and current capital regulations, § 628.10(d) of the final rule confirms FCA's authority to require an institution to hold a different amount of regulatory capital from what is otherwise required under the final rule, if we determine that the institution's regulatory capital is not commensurate with its credit, operational, or other risks. Therefore, the FCA will continue to hold each System institution accountable to maintain sufficient capital commensurate with the level and nature of the risks to which it is exposed. This may require capital significantly above the minimum requirements, depending on the institution's activities and risk profile. Section D below describes the requirement for overall capital adequacy of System institutions and the supervisory assessment of an institution's capital adequacy.

B. Leverage Ratio

Consistent with Basel III and the U.S. rule, we proposed a tier 1 leverage ratio for all System institutions. We proposed a minimum leverage ratio of 5 percent, of which at least 1.5 percent of non-risk weighted total assets must be URE and

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[49] For example, an institution's retail loan to a large agribusiness can be collateralized by all assets of the borrower and can include financial, reporting, and negative covenants similar to those the commenters note exist in the GFA.

[50] The bank can authorize the association to obtain funding elsewhere. Sections 2.2(12) and 2.12(16) of the Act.

[51] Currently, no System GFA has a term longer than 3 years.

URE equivalents.[52] FCA's proposal differed in two respects from the leverage ratio adopted by the Federal regulatory banking agencies: There is no minimum URE and URE equivalents requirement in their leverage ratio, and their minimum requirement for the majority of commercial banks is 4 percent. We received numerous comments opposing the 5-percent tier 1 leverage ratio requirement and the 1.5-percent URE and URE equivalents minimum requirements in the System Comment Letter and from individual System banks and associations. We discuss their comments in Section I.E.6 above.

In response to the comments, we are adopting a 4-percent minimum leverage ratio, of which at least 1.5 percent must be URE and URE equivalents, and we are adding a leverage buffer of 1 percent in the final rule. We believe this revised requirement in the final rule addresses commenters' concerns, is not unduly restrictive, and will ensure that System institutions hold sufficient capital to continue to fulfill their mission as a GSE. In addition, we have revised the definition of URE equivalents to require institutions to designate equities as URE equivalents in their bylaws or board resolutions, and we have added corresponding language to paragraph (d) of the capital planning requirements in § 615.5200. We have also provided an exception to the offset prohibition for offsets required by court order and under § 615.5290.

The tier 1 leverage ratio buffer incorporates the same restrictions as the capital conservation buffer but is based on a 1-percent buffer as opposed to a 2.5-percent buffer. To avoid restrictions on cash dividend payments, cash patronage payments, and allocated equity redemptions (collectively, capital distributions) or discretionary executive bonuses, an institution's tier 1 leverage ratio must be at least 1 percent above the minimum requirement of 4 percent. The tier 1 leverage ratio buffer consists of tier 1 capital. If the institution's tier 1 leverage ratio is below the minimum requirement of 4 percent, the institution's leverage buffer is zero. There will be no phase-in for the leverage buffer as our analysis based on September 30, 2015 call reports shows that all System institutions will be above the 1 percent leverage buffer.

The maximum leverage payout ratio is the percentage of eligible retained income that a System institution would be allowed to pay out in capital distributions and discretionary bonuses during the current calendar quarter and is determined by the amount of the tier 1 leverage ratio buffer held by the institution during the previous calendar quarter. The eligible retained income computation is the same as for the capital conservation buffer.

A System institution's maximum leverage payout amount for the current calendar quarter is equal to its eligible retained income multiplied by the applicable maximum leverage payout ratio in accordance with table 2 in § 628.11. An institution with a leverage buffer that is greater than 1 percent is not subject to a maximum leverage payout amount under this provision (although capital distributions without FCA prior approval may be restricted by other provisions in this proposed rule). If the applicable leverage buffer falls under 1 percent, the institution would remain subject to payout restrictions until it raises its leverage buffer above 1 percent. In addition, a System institution would not generally be able to make capital distributions or pay discretionary bonuses during the current calendar quarter if its eligible retained income is negative and its capital conservation buffer is less than 2.5 percent, or its leverage buffer is less than 1 percent, as of the end of the previous quarter. In the event that a System institution's capital requirements fall below the 1-percent leverage buffer as well as the 2.5-percent capital conservation buffer, when calculating the applicable payout amount, the institution must use the lower between the maximum payout ratio and the maximum leverage payout ratio. For example, under the capital conservation buffer, if an institution's total capital regulatory ratio is 10.25 percent (fully phased-in), based on table 1 in § 628.11, the maximum payout ratio would be 60 percent. Under the leverage buffer, the same institution's tier 1 leverage ratio is 4.6 percent and based on table 2 in § 628.11, the maximum leverage payout ratio would be 40 percent. As the leverage buffer is the lower maximum payout between the two, in this example, the payout ratio the System institution must use is 40 percent.

The leverage buffer is divided into quartiles, with greater restrictions on capital distributions and discretionary bonus payments as the leverage buffer falls closer to 0. Payouts are restricted to 60 percent of eligible retained income if the buffer is above 0.75 percent but at or below 1 percent. When the buffer is above 0.50 percent but less than or equal to 0.75 percent, the payout would be restricted to 40 percent of eligible retained income. When the buffer is above 0.25 percent but less than or equal to 0.50 percent, the payout would be restricted to 20 percent of eligible retained income. A leverage buffer of 0.25 percent or below would result in a 0 percent payout.

For the reasons discussed above, the proposed requirement of the tier 1 leverage ratio consisting of at least 1.5 percent of URE and URE equivalents is not modified in the final rule.

C. Capital Conservation Buffer

Consistent with Basel III and the U.S. rule, we proposed a capital conservation buffer to enhance the resilience of System institutions throughout financial cycles. To avoid restrictions on cash payments for capital distributions or discretionary executive bonuses, an institution's risk weighted regulatory capital ratios must be at least 2.5 percent above the minimums when the buffer is fully phased in. The proposed buffer provided an incentive for institutions to hold capital well above the minimum required levels to ensure that they would meet the regulatory minimums even during stressful conditions.

The FCA is adopting the capital conservation buffer requirements in § 628.11 with minor modifications from the proposed rule, as described below.

The capital conservation buffer consists of tier 1 capital and is the lowest of the following risk weighted measures:

- The institution's CET1 ratio minus its minimum CET1 ratio;
- The institution's tier 1 ratio minus its minimum tier 1 ratio; and
- The institution's total capital ratio minus its minimum total capital ratio.

If any of the institution's risk weighted ratios are at or below the minimum required ratios, the institution's capital conservation buffer is zero.

The maximum payout ratio is the percentage of eligible retained income that a System institution is allowed to pay out in capital distributions and discretionary bonuses during the current calendar quarter and is determined by the amount of the capital conservation buffer held by the institution during the previous calendar quarter. Eligible retained income is defined as the institution's net income as reported in its quarterly call reports to the FCA for the four calendar quarters preceding the current calendar quarter, net of any capital distributions, certain discretionary bonus payments, and associated tax effects not already reflected in net income.

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[52] Only System banks are subject to the net collateral ratio requirement, which has similarities to that of a leverage ratio, the tier 1 leverage ratio would replace the net collateral ratio requirement for System banks.

The System Comment Letter expressed concerns over the proposed definition of eligible retained income. The System stated that the proposed definition results in an excess deduction based on prior year distributions from current eligible retained income because the patronage distribution practices of cooperatives create a far more restrictive requirement than applicable to commercial banks. The System included an example that, to determine the eligible retained income in the first quarter of 2015, this would be based on 2014 net income, less the patronage distribution of 2013 that was paid in the first quarter of 2014. The System asserted that this is inappropriate and that deductions for patronage distributions should be aligned with when the earnings were generated.

The final rule adopts the proposed definition of eligible retained income without change. We believe that this definition of eligible retained income is appropriate and is essentially the same as the definition in the U.S. rule. We believe eligible retained income must reflect a System institution's most recent 12-month period at each quarter end, so that restrictions on capital distributions and discretionary payments to executive officers are based on the institution's most recent performance results. If a System institution declares a dividend payment or patronage payment in a specified year, the institution can recognize and accrue the dividend payment or patronage payment in the same year it was earned; that way it is reflected in that specified year's income. This could result in a change of practice for many institutions that do not recognize and accrue the patronage income in the year it was earned, but rather the following year when it is distributed. If an institution chooses not to change its patronage payment accounting practices, this treatment remains appropriate because at the declaration date, the dividend payment and patronage payment is deducted from the current year's earnings, even if it was based on the previous year's earnings. Furthermore, if the System institution wants to declare a dividend payment or patronage payment in the same quarter of every year, it will not be subject to a double deduction under the regulation.

We believe for this calculation that the declaration date determines what year the dividend payment and patronage payment are attributed. As the calculation is a rolling 12-month calculation for eligible retained income calculated each quarter, we believe institutions may decide to declare the dividend payment or patronage dividend payments the same quarter, in order to make this calculation comparable from year to year and quarter to quarter. To do otherwise would hinder both the FCA's and the System's ability to conduct quarter to quarter comparisons.

A System institution's maximum payout amount under the capital conservation buffer for the current calendar quarter is equal to its eligible retained income multiplied by the applicable maximum payout ratio in accordance with table 1 in § 628.11. An institution with a capital conservation buffer that is greater than 2.5 percent is not subject to a maximum payout amount under this provision (although capital distributions without FCA prior approval may be restricted by other provisions in this rule). If an institution's CET1, tier 1, or total capital ratio is 2.5 percent or less above the minimum ratio, the maximum payout ratio also declines. The institution remains subject to payout restrictions until it raises its capital conservation buffer above 2.5 percent. In addition, a System institution will not generally be able to make capital distributions or pay discretionary bonuses during the current calendar quarter if its eligible retained income is negative and its capital conservation buffer is less than 2.5 percent as of the end of the previous quarter.

The capital conservation buffer is divided into quartiles, with greater restrictions on capital distributions and discretionary bonus payments as the capital conservation buffer falls closer to 0 percent. When the buffer is fully phased in, payouts are restricted to 60 percent of eligible retained income if the buffer is above 1.875 percent but at or below 2.5 percent. When the buffer is above 1.25 percent but less than or equal to 1.875 percent, the payout is restricted to 40 percent of eligible retained income. When the buffer is above 0.625 percent but equal to or below 1.25 percent, the payout is restricted to 20 percent of eligible retained income. A capital conservation buffer of 0.625 percent or below results in a 0 percent payout.

We have made several changes to the definition of "capital distribution" to ensure the intent of the buffers—to conserve capital—is fulfilled, and to ensure comparability with the U.S. rule. In paragraphs (A) and (B) of § 628.11(a)(2)(vii), we have specified that the replacement capital instrument must be purchased capital. In paragraph (D) of § 628.11(a)(2)(vii), we have replaced the reference to "any tier 2 capital instrument" with a reference to "any capital instrument other than a tier 1 capital instrument" to ensure inclusion of any dividend declarations or interest payments on capital instruments that are not included in tier 1 or tier 2 capital. The final rule defines a capital distribution as:

- A reduction of tier 1 capital through the repurchase or redemption of a tier 1 capital instrument or by other means, unless the redeemed capital is replaced in the same quarter by purchased tier 1 qualifying capital;
- A reduction of tier 2 capital through the repurchase, or redemption prior to maturity, of a tier 2 capital instrument or by other means, unless the redeemed capital is replaced in the same quarter by purchased qualifying tier 1 or tier 2 capital;
- A dividend declaration or payment on any tier 1 capital instrument;
- A dividend declaration or interest payment on any capital instrument other than a tier 1 capital instrument if the institution has full discretion to suspend such payments permanently or temporarily without triggering an event of default;
- A cash patronage payment declaration or payment;
- A patronage payment declaration in the form of allocated equities that do not qualify as tier 1 or tier 2 capital;[53] or
- Any similar transaction that the FCA determines to be in substance a capital distribution.[54]

The rule defines a discretionary bonus payment as a payment made to a senior officer of a System institution, where:

- The System institution retains discretion whether to pay the bonus and how much to pay until it awards the payment to the senior officer;
- The System institution determines the amount of the bonus without prior promise to, or agreement with, the senior officer; and
- The senior officer has no express or implied contractual right to the bonus payment.

The term "senior officer" is already defined in § 619.9310 as the Chief Executive Officer, the Chief Operations Officer, the Chief Financial Officer, and the General Counsel, or persons in similar positions, and any other person responsible for a major policy-making function.[55]

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[53] A patronage declaration or payment in the form of allocated equities that qualify as tier 1 capital is not a reduction in tier 1 capital. It is merely a reclassification from one tier 1 capital element into a different tier 1 capital element.

[54] We note that the Federal regulatory banking agencies replaced the term "capital distribution" with "distribution" in their final rule. We have decided to use the term "capital distribution" to avoid potential confusion with other types of distributions that do not meet the definition for purposes of applying the capital conservation buffer.

[55] The FCA considers this definition substantively identical to the definition of "executive officer" used in the Federal regulatory banking agencies' rules on the capital conservation buffer.

The purpose of limiting restrictions on discretionary bonus payments to senior officers is to focus these measures on the individuals within an institution who could expose the institution to the greatest risk. We note that the institution may otherwise be subject to limitations on capital distributions under other provisions in this rule. In addition, we retain authority to approve a capital distribution or bonus payment if we determine that the payment would not be contrary to the purposes of the capital conservation buffer or the safety and soundness of the institution.

D. Supervisory Assessment of Overall Capital Adequacy

Section 628.10(d)(1) of the proposed rule required each System institution to maintain capital commensurate with the level and nature of all risks to which it was exposed and to have a process for assessing its overall capital adequacy in relation to its risk profile, as well as a comprehensive strategy for maintaining an appropriate level of capital. We did not receive any comments on this proposal and adopt it as final without modifications.

System institutions should have internal processes to assess capital adequacy that reflect a full understanding of risks and to ensure sufficient capital is held. Our supervisory assessment of capital adequacy must take account of the internal processes for capital adequacy, as well as risks and other factors that can affect an institution's financial condition, including the level and severity of problem assets and total surplus exposure to operational and interest rate risk. For this reason, a supervisory assessment of capital adequacy may differ significantly from conclusions that might be drawn solely from the level of the institution's risk-based capital ratios.

The FCA expects System institutions generally to operate with capital levels well above the minimum risk-based ratios and to hold capital commensurate with the level and nature of the exposed risk. For example, System institutions that are growing or that anticipate growth in the near future should maintain strong capital levels substantially above the minimums and should not allow significant weakening of financial strength below such levels to fund their growth. System institutions with high levels of risk are also expected to operate with capital well above the minimum levels. The supervisory assessment also evaluates the quality and trends in an institution's capital composition, including the share of common cooperative equities and URE and equivalents.

The supervisory assessment may include such factors as whether the institution has merged recently, entered new activities, or introduced new products. It also considers whether an institution (1) is receiving special supervisory attention from FCA, (2) has or is expected to have losses resulting in capital inadequacy, (3) has significant exposure due to risks from concentrations in credit or nontraditional activities, (4) has significant exposure to interest rate risk or operational risk, or (5) could be adversely affected by the activities or condition of an affiliated System institution.

The supervisory assessment also evaluates the comprehensiveness and effectiveness of a System institution's capital as required by § 615.5200 of existing FCA regulations.[56] An effective capital planning process requires a System institution to assess its risk exposures, develop strategies for mitigating those risks, and set capital adequacy goals relative to its risks and prospective economic conditions. Evaluation of an institution's capital adequacy process is commensurate with the institution's size, sophistication, and risk profile.

III. Definition of Capital

A. Capital Components and Eligibility Criteria for Regulatory Capital Instruments

1. Common Equity Tier 1 (CET1) Capital

Section 628.20(b) of the proposed rule defined a System institution's CET1 as the sum of URE and common cooperative equities, minus the regulatory adjustments and deductions described in § 628.22. As discussed in Section I.E.1 of this preamble, we have adapted the criteria for the common cooperative equities in accordance with footnote 12 of Basel III, which states that the criteria for non-joint stock companies, including mutuals and cooperatives, should take into account their legal structure and constitution.[57]

Basel III established 14 criteria a banking organization must meet to include an instrument in CET1 capital; the U.S. rule has 13 criteria. These criteria ensure that the instrument will be available to absorb losses at the banking organization on a going-concern basis. Several of the criteria provide that the instrument represents the most subordinated claim in liquidation, is entitled to a claim on residual assets proportional to its share of issued capital, and must take the first and proportionately greatest share of any losses as they occur.

Unlike joint-stock banks, System institutions have priorities of impairment among the various classes of member stock and allocated equities, and typically, all current and former members are entitled to the residual assets, based on historic patronage payments, in a liquidation of the institution. However, all common cooperative equities are impaired and depleted before all other instruments. Therefore, we proposed to replace some of the Basel III and U.S. rule criteria with criteria providing that the instrument must represent a claim subordinated to all other equities of an institution in liquidation, and the holder would receive payment only after all general creditors and debt holders are paid. We did not receive comments on the liquidation-related criteria and adopt them in the final rule as proposed.

Another CET1 criterion of Basel III and the U.S. rule—a criterion that also applies to additional tier 1 capital and tier 2 capital—is that the banking organization must do nothing to create an expectation at issuance that the instrument will be redeemed, nor do the statutory or contractual terms provide any feature that might give rise to such an expectation. In the System, institutions issue or allocate some cooperative equities that are never retired and that do not give rise to redemption or revolvement expectations by member-borrowers. Other cooperative equities, by contrast, are redeemed frequently and routinely. Through this practice, System institutions can create expectations on the part of their members that these purchased and allocated equities will be redeemed.

In the preamble to the proposed rule, we described our concern that the "expectation" requirement of Basel III and the U.S. rule could reasonably be interpreted to disallow cooperative equities redeemed or revolved by System institutions. We therefore proposed to permit System institutions to include cooperative equities in CET1 and tier 2 capital if they adopted bylaws committing the institution not to redeem or revolve for 10 years in the case of CET1 equities and for 5 years in the case of tier 2 equities. We also required the bylaw to state that the institution would not offset an instrument against a member-borrower's loan in default without prior FCA approval, to ensure the permanence and stability of the included equities. The proposed rule provided an exception to the minimum redemption and revolvement periods that permitted institutions to redeem or revolve an amount of member stock equal to the minimum stock purchase requirement set forth in the Farm Credit Act. The statutory minimum is $1,000 or 2 percent of the member's loan or loans, whichever is less. This member stock exception is similar to exceptions for member stock redemptions adopted by a number of European countries. There is a detailed discussion of this exception in the preamble to our proposed rule.[58]

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[56] As discussed below, the final rule revises existing § 615.5200 to require the capital planning to include the new ratios.

[57] Basel III framework footnote 12 to "Criteria for classification as common shares for regulatory capital purposes."

We received extensive comments from System institutions on the 10-year minimum redemption and revolvement period for CET1 capital and the proposed bylaw requirement that we discuss in Part I.E.4 above. Commenters also asked us to provide exceptions permitting, without FCA prior approval, offsets of equities against loans in default or restructured loans and redemptions and revolvements of equities owned by the estates of former borrowers. As we described above, in the final rule we have given institution boards the option to adopt an annual resolution affirming the institution's commitment to the minimum redemption and revolvement periods as an alternative to adopting a capitalization bylaw. We have also adopted a minimum 7-year period for CET1 capital and retained the minimum 5-year period for tier capital. The final rule permits equity retirements mandated by final order of a court of competent jurisdiction and offsets mandated by § 615.5290, as well as redemptions and revolvements of the equities owned by the estate of a former borrower before the end of the minimum redemption and revolvement period. Such redemptions and revolvements may be made under the safe harbor provision in § 628.20(f) if they fit within the dollar limit.

The final rule adds new paragraph (d) to the capital planning requirements in § 615.5200, describing the requirements of the capital bylaw or board resolution an institution must adopt in order to include otherwise eligible purchased and allocated equities in CET1 and tier 2 capital. The institution must undertake or commit to obtain prior approval from the FCA under § 628.20(f) before redeeming or revolving CET1 equities less than 7 years after issuance (in the case of purchased equities) or allocation (the date of declaration in the case of allocated equities). For additional tier 1 equities, the institution must commit itself to obtain prior FCA approval before redeeming or calling equities. For tier 2 equities, the institution must make the same commitment not to redeem or revolve the equities less than 5 years after issuance or allocation without FCA approval. In addition, the institution must commit to obtaining approval from the FCA to change the regulatory capital treatment of the equities included in the new capital ratios, as follows:

(i) Redesignating URE equivalents as equities that the institution may exercise its discretion to redeem other than upon dissolution or liquidation;

(ii) Removing equities or other instruments from CET1, additional tier 1, or tier 2 capital other than through repurchase, redemption or revolvement; and

(iii) Redesignating equities included in one component of regulatory capital (CET1 capital, additional tier 1 capital, or tier 2 capital) as included in another component of regulatory capital.

The restrictions on removing or redesignating equities would, ensure that equities included in CET1 could not be redesignated by an institution as tier 2 equities so that the institution could redeem or revolve them after only 5 years. Similarly, equities cannot be removed from tier 1 and tier 2 capital without FCA prior approval and then redeemed or revolved in less than 5 years. We note that, to obtain the FCA approvals described here, the institutions must submit a request under paragraphs (f)(1) through (4) of § 628.20 and cannot rely on the deemed prior approval or "safe harbor" described in paragraph (f)(5).

The System Comment Letter objected to the rule's requirement that System institutions keep records of when they issue or allocate common cooperative equities included in CET1 and tier 2 (the comment refers to this as "date-stamping"). The System stated that date-stamping requires significant unnecessary administrative burden and is not logical because it does not "recognize the portfolio nature of cooperative equities." The System asserted that, for long-time borrowers, it does not matter whether one share of their equity is held for 2 years and another share is held for 10 years because the borrower has committed to maintain a stable and predictable level of investment related to its business with the institution. The System suggested that institutions be permitted to comply with the minimum redemption and revolvement requirements by using a "loan-based approach" instead of a date-stamped approach.

The comment that cooperative equities have a portfolio nature is not clear to us. As for date-stamping, we disagree that it is a significant burden to keep these records. It is our understanding that the relevant software programs are available and inexpensive. Moreover, System associations have been required since 1997 to maintain records of when they issue or allocate common cooperative equities in order to include such equities in their core surplus ratios. System banks have not been required to maintain such records because they cannot include in core surplus the equities they issue or allocate to other System institutions. Currently, the System banks have various "loan-based" programs that require their borrowers to hold investments in their bank equal to a percentage of the outstanding loan amount. A bank may be able to include such equities in its CET1 and tier 2 capital ratios if its loan-based program operates so as to ensure that the equities meet the rule's applicable minimum revolvement periods and other criteria. The FCA will consider approving such requests from System institutions under § 628.1(d)(2)(ii).

As for the request to grandfather existing allocated equities for which the institution has no record of the date of allocation or issuance, we believe that most, if not all, institutions' records do contain the necessary data on when a borrower purchased or received equities. Any institution with insufficient records may submit to the FCA a request to include the equities in question along with an explanation of why the records are insufficient. We will consider whether to permit the institution to include such equities, or a portion of such equities, on a temporary basis.

The final rule requires that the common cooperative equities included in CET1 satisfy all the following criteria:

(1) The instrument is issued directly by the System institution and represents a claim subordinated to all preferred stock, all subordinated debt, and all liabilities in a receivership, insolvency, liquidation, or similar proceeding of the System institution;

(2) If the holder of the instrument is entitled to a claim on the residual assets of the System institution, the claim will be paid only after all general creditors, subordinated debt holders, and preferred stock claims have been satisfied in a receivership, insolvency, liquidation, or similar proceeding;

(3) The instrument has no maturity date, can be redeemed only at the

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[58] *See* 79 FR 52824.

discretion of the System institution and with the prior approval of FCA, and does not contain any term or feature that creates an incentive to redeem;

(4) The System institution did not create, through any action or communication, an expectation that it will buy back, cancel, revolve, or redeem the instrument, and the instrument does not include any term or feature that might give rise to such an expectation, except that the establishment of a minimum revolvement period of 7 years or more, or the practice of revolving or redeeming the instrument no less than 7 years after issuance or allocation, will not be considered to create such an expectation;

(5) Any cash dividend payments on the instrument are paid out of the System institution's net income or unallocated retained earnings, and are not subject to a limit imposed by the contractual terms governing the instrument;

(6) The System institution has full discretion at all times to refrain from paying any dividends without triggering an event of default, a requirement to make a payment-in-kind, or an imposition of any other restrictions on the System institution;

(7) Dividend payments and other distributions related to the instrument may be paid only after all legal and contractual obligations of the System institution have been satisfied, including payments due on more senior claims;

(8) The holders of the instrument bear losses as they occur before any losses are borne by holders of preferred stock claims on the System institution and holders of any other claims with priority over common cooperative equity instruments in a receivership, insolvency, liquidation, or similar proceeding;

(9) The instrument is classified as equity under GAAP;

(10) The System institution, or an entity that the System institution controls, did not purchase or directly or indirectly fund the purchase of the instrument, except that where there is an obligation for a member of the institution to hold an instrument in order to receive a loan or service from the System institution, an amount of that loan equal to the minimum borrower stock requirement under section 4.3A of the Farm Credit Act will not be considered as a direct or indirect funding where:

(a) The purpose of the loan is not the purchase of capital instruments of the System institution providing the loan; and

(b) The purchase or acquisition of one or more member equities of the institution is necessary in order for the beneficiary of the loan to become a member of the System institution;

(11) The instrument is not secured, not covered by a guarantee of the System institution, and is not subject to any other arrangement that legally or economically enhances the seniority of the instrument;

(12) The instrument is issued in accordance with applicable laws and regulations and with the institution's capitalization bylaws;

(13) The instrument is reported on the System institution's regulatory financial statements separately from other capital instruments; and

(14) The System institution's capitalization bylaws or a resolution adopted by its board of directors and re-affirmed on an annual basis provides that it will not redeem or revolve the instrument for a period of at least 7 years after issuance or allocation (other than under § 615.5290), and that it will not reduce the original redemption or revolvement period to less than 7 years without the prior approval of the FCA, except that the minimum statutory borrower stock described under paragraph (b)(1)(x) of § 628.20 may be redeemed without a minimum period outstanding after issuance and without the prior approval of the FCA.

2. Additional Tier 1 (AT1) Capital

The criteria for AT1 are comparable to Basel III and the Federal regulatory banking agencies' rules. AT1 includes primarily noncumulative perpetual preferred stock issued by System institutions and is subject to certain adjustments and deductions. Qualifying instruments are primarily stock issued by System banks to third-party investors, though all System institutions have authority to issue such stock. AT1 does not include common cooperative equities.

The System Comment Letter and an individual affiliated with a commercial bank commented that a clause in the proposed criterion relating to distributions (paragraph (8) below and § 628.20(c)(1)(viii) in the final rule) was not part of the criterion in Basel III or the final U.S. rule. The clause in question is, "and are not subject to a limit imposed by the contractual terms governing the instrument." In the proposed rule, we mistakenly included the clause in this criterion. We have deleted it in the final rule.

The criteria for inclusion in AT1 capital are:

(1) The instrument is issued and paid-in;

(2) The instrument is subordinated to general creditors and subordinated debt holders of the System institution in a receivership, insolvency, liquidation, or similar proceeding;

(3) The instrument is not secured, not covered by a guarantee of the System institution and not subject to any other arrangement that legally or economically enhances the seniority of the instrument;

(4) The instrument has no maturity date and does not contain a dividend step-up or any other term or feature that creates an incentive to redeem;

(5) If callable by its terms, the instrument may be called by the System institution only after a minimum of 5 years following issuance, except that the terms of the instrument may allow it to be called earlier than 5 years upon the occurrence of a regulatory event that precludes the instrument from being included in AT1 capital, or a tax event. In addition:

(a) The System institution must receive prior approval from FCA to exercise a call option on the instrument.

(b) The System institution does not create at issuance of the instrument, through any action or communication, an expectation that the call option will be exercised.

(c) Prior to exercising the call option, or immediately thereafter, the System institution must either: Replace the instrument to be called with an equal amount of instruments that meet the criteria for a CET1 or AT1 capital instrument;[59] or demonstrate to the satisfaction of FCA that following redemption, the System institution will continue to hold capital commensurate with its risk;

(6) Redemption or repurchase of the instrument requires prior approval from FCA;

(7) The System institution has full discretion at all times to cancel dividends or other capital distributions on the instrument without triggering an event of default, a requirement to make a payment-in-kind, or an imposition of other restrictions on the System institution except in relation to any capital distributions to holders of common cooperative equity instruments or other instruments that are *pari passu* with the instrument.

(8) Any capital distributions on the instrument are paid out of the System institution's net income, unallocated retained earnings, or surplus related to other AT1 capital instruments;

(9) The instrument does not have a credit-sensitive feature, such as a

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[59] Replacement can be concurrent with redemption of existing AT1 capital instruments.

dividend rate that is reset periodically based in whole or in part on the System institution's credit quality, but may have a dividend rate that is adjusted periodically independent of the System institution's credit quality, in relation to general market interest rates or similar adjustments;

(10) The paid-in amount is classified as equity under GAAP;

(11) The System institution did not purchase or directly or indirectly fund the purchase of the instrument;

(12) The instrument does not have any features that would limit or discourage additional issuance of capital by the System institution, such as provisions that require the System institution to compensate holders of the instrument if a new instrument is issued at a lower price during a specified timeframe; and

(13) The System institution's capitalization bylaws or a resolution adopted on an annual basis by its board of directors provides that it will not call or redeem the instrument without the prior approval of the FCA.

Notwithstanding the criteria for AT1 capital instruments referenced above, an instrument with terms that provide that the instrument may be called earlier than 5 years upon the occurrence of a rating agency event does not violate the minimum 5-year issuance requirement provided that the instrument was issued and included in a System institution's core surplus capital prior to the effective date of the final rule, and that such instrument satisfies all other criteria under § 628.20(c).

3. Tier 2 Capital

The FCA proposed to include in tier 2 capital the sum of tier 2 capital instruments that satisfy the applicable criteria, plus ALL up to 1.25 percent of risk weighted assets, less any applicable adjustments and deductions. The criteria are similar to those in Basel III and the U.S. rule, except that common cooperative equities that are not includable in CET1 may be included in tier 2 if they meet the applicable criteria.

The System Comment Letter suggested that we eliminate the minimum 5-year period for redemptions of perpetual stock and allocated equities. As discussed above in Section I.E.3 above, we have decided to retain the minimum 5-year period as it is comparable to the tier 2 required minimum term for term stock and the 5-year no-call period for other equities.

We have revised the bylaw requirement to permit compliance by an annual board resolution, and we have added the 2 exceptions to redemption or revolvement before the 5-year minimum period, which are the redemption or revolvement of equities owned by the estate of a former borrower and equities mandated to be retired by a court of competent jurisdiction.

The criteria for instruments (plus related surplus) included in tier 2 capital are:

(1) The instrument is issued and paid-in, is a common cooperative equity, or is member equity purchased in accordance with § 628.20(d)(1)(viii) of the proposed rule;

(2) The instrument is subordinated to general creditors of the System institution;

(3) The instrument is not secured, not covered by a guarantee of the System institution and not subject to any other arrangement that legally or economically enhances the seniority of the instrument in relation to more senior claims;

(4) The instrument has a minimum original maturity of at least 5 years. At the beginning of each of the last 5 years of the life of the instrument, the amount that is eligible to be included in tier 2 capital is reduced by 20 percent of the original amount of the instrument (net of redemptions) and is excluded from regulatory capital when the remaining maturity is less than 1 year. In addition, the instrument must not have any terms or features that require, or create significant incentives for, the System institution to redeem the instrument prior to maturity;[60]

(5) The instrument, by its terms, may be called by the System institution only after a minimum of 5 years following issuance, except that the terms of the instrument may allow it to be called sooner upon the occurrence of an event that would preclude the instrument from being included in tier 2 capital, or a tax event. In addition:

(a) The System institution must receive the prior approval of FCA to exercise a call option on the instrument.

(b) The System institution does not create at issuance, through action or communication, an expectation the call option will be exercised.

(c) Prior to exercising the call option, or immediately thereafter, the System institution must either: Replace any amount called with an instrument that is of equal or higher quality regulatory capital under this section;[61] or demonstrate to the satisfaction of FCA that following redemption, the System institution would continue to hold an amount of capital that is commensurate with its risk;

(6) The holder of the instrument must have no contractual right to accelerate payment of principal, dividends, or interest on the instrument, except in the event of a receivership, insolvency, liquidation, or similar proceeding of the System institution;

(7) The instrument has no credit-sensitive feature, such as a dividend or interest rate that is reset periodically based in whole or in part on the System institution's credit standing, but may have a dividend rate that is adjusted periodically independent of the System institution's credit standing, in relation to general market interest rates or similar adjustments;

(8) The System institution has not purchased and has not directly or indirectly funded the purchase of the instrument, except that where common cooperative equity instruments are held by a member of the institution in connection with a loan, and the institution funds the acquisition of such instruments, that loan shall not be considered as a direct or indirect funding where:

(a) The purpose of the loan is not the purchase of capital instruments of the System institution providing the loan;

(b) The purchase or acquisition of one or more capital instruments of the institution is necessary in order for the beneficiary of the loan to become a member of the System institution; and

(c) The capital instruments are in excess of the statutory minimum stock purchase amount;

(9) Redemption of the instrument prior to maturity or repurchase is at the discretion of the System institution and requires the prior approval of the FCA; and

(10) If the instrument is a common cooperative equity, the System institution's capitalization bylaws or a resolution adopted by its board of directors and re-affirmed on an annual basis provides that it will not, except with the prior approval of the FCA, redeem such equity included in tier 2 capital for a period of at least 5 years after allocating it to a member, except that equities owned by the estate of a former borrower and equities required to be retired by final order of a court of competent jurisdiction may be redeemed without a minimum period outstanding after allocation.

4. FCA Approval of Capital Elements

Proposed § 628.20(e) required a System institution to obtain prior approval to include a new capital element in its CET1 capital, AT1 capital, or tier 2 capital unless the element was equivalent, in terms of capital quality and ability to absorb losses with respect to all material terms, to a regulatory element the FCA had already determined may be included in regulatory capital. After the FCA determined that an institution could include an element in regulatory capital, it would make its decision publicly available.

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[60] An instrument that by its terms automatically converts into a tier 1 capital instrument prior to 5 years after issuance complies with the 5-year maturity requirement of this criterion.

[61] A System institution may replace tier 2 or tier 1 capital instruments concurrent with the redemption of existing tier 2 capital instruments.

We did not receive any comments on this proposal and adopt it as final without modification.

5. FCA Prior Approval Requirements for Cash Patronage, Dividends, and Redemptions; Safe Harbor

As described above, the proposed rule required FCA prior approval for the redemption of equities included in tier 1 and tier 2, consistent with Basel III and the U.S. rule. The proposal also required FCA prior approval of cash dividend payments and cash patronage payments. Prior approval is not a requirement of the Basel III framework but is a requirement imposed by statute or regulation on commercial banks and other federally chartered banking organizations regulated by the Federal banking regulatory agencies.[62]

We also proposed a "safe harbor" provision in § 628.20(f) permitting institutions to pay cash dividend payments, cash patronage payments, and to redeem equities with "deemed" FCA prior approval if the payments were within the specified parameters. Under the proposed safe harbor, an institution had "deemed" prior approval for capital distributions to make cash dividend payments, cash patronage payments, or redemptions and revolvements of qualifying common cooperative equities provided that, after such capital distributions, the dollar amount of the System institution's CET1 capital equaled or exceeded the dollar amount of CET1 capital on the same date in the previous calendar year and the institution continued to comply with all regulatory capital requirements and supervisory or enforcement actions. The common cooperative equities that qualified for redemption or revolvement under the safe harbor were the minimum member stock requirement of $1,000 or 2 percent of the loan, whichever is less; equities included in CET1 capital that were issued or allocated at least 10 years ago; and equities included in tier 2 capital that were issued or allocated at least 5 years ago.

System institutions have not generally had to obtain FCA prior approval before paying dividend payments or patronage payments or redeeming equities under current regulations, and the Farm Credit Act does not require prior approval. However, prior approval of equity redemptions is a fundamental principle of the Basel III framework and U.S. rule, and there are limits on the cash dividends commercial banks may pay without prior approval of their Federal banking regulator. In order for the regulatory capital framework of System institutions to be comparable to the regulatory capital framework of the U.S. banking organizations, it was necessary to include these prior approval requirements in our proposed rule. However, in acknowledgment of the common cooperative equity redemption and revolvement practices of System institutions, we permitted a limited amount of these redemptions and revolvements under the safe harbor "deemed" prior approval. We stated our belief that most System institutions would be able to pay cash dividend payments, cash patronage payments, and redeem equities within the safe harbor at the same levels that they pay currently.

The System Comment Letter made a number of comments, suggestions, and requests with respect to the prior approval requirements and the safe harbor provision. Two comments on the safe harbor's cap, or maximum payment amount, are discussed above in Section I.E.7 of this preamble. With respect to the prior approval process, the System expressed concern that the 30-day approval process would be burdensome and unworkable and suggested the process be streamlined for institutions with high FIRS ratings, with FCA granting approvals in as short a time as one day. A further suggestion was that the FCA could pre-approve all contemplated capital distributions under the capital plan required by § 615.5200.

The FCA has decided to retain its 30-day review in the final rule. We expect any proposed cash dividend payments, cash patronage payments, redemptions and revolvements that must be submitted to us will have been long planned by the institution, and we need sufficient time for our review. We note that a 30-day period is comparable to the review periods of the Federal banking regulatory agencies.

The FCA has decided not to adopt the System's suggestion to "pre-approve" all capital distributions in an institution's capital plan required under § 615.5200. While FCA staff reviews the capital plans submitted by institutions, we do not formally approve the plans. However, as described above in the criteria for CET1 and tier 2 capital, we have modified the criteria and the safe harbor provision to provide two additional exceptions, in response to a comment the System made with respect to the capital plan requirements in § 615.5200.

In the proposed rule, we deleted a provision in existing § 615.5200(b) pertaining to redemptions or revolvements of equities in connection with a loan default or the death of a former borrower. The deleted provisions required an institution to make a prior determination that such redemptions or revolvements were in the best interest of the institution and also required the institution to charge off an amount of the indebtedness equal to the amount of the equities that were redeemed or revolved. The System approved the deletions as eliminating a restriction on System institutions' "absolute statutory right" to retire cooperative equities in the event of loan default and restructuring without regard to any restrictions on the equities included in tier 1 and tier 2 capital in new part 628. The System asked us to clarify whether institutions will also be able to continue to redeem or revolve equities in connection with the death of a former borrower with regard to the part 628 restrictions.

As we have discussed at some length here and in the preamble to the proposed rule, the required prior regulatory approval of equity retirements is a principle underlying the Basel III framework and the U.S. rule. Without the prior approval requirement, the new tier 1 and tier 2 framework we are adopting would not be comparable to the Basel III framework and the U.S. rule. System institutions forgo their discretion to redeem or revolve equities included in tier 1 and tier 2, and they must commit to obtain prior approval (or must rely on the safe harbor "deemed" prior approval) before redeeming or revolving the equities. The prior approval requirements apply to redemptions and revolvements related to a loan default or restructuring and to equities of a deceased former borrower. Institutions will thus have to submit a request to the FCA for prior approval or will have to redeem or revolve the equities within the safe harbor parameters. However, we are aware that the safe harbor cannot be utilized to redeem or revolve CET1 equities that have been outstanding for less than the minimum 7-year holding period or for tier 2 equities that have been outstanding for less than 5 years. Therefore, we have modified the proposed safe harbor provision to add 2 exceptions suggested by the System (with modifications) to the minimum retention periods in the safe harbor provision, as well as an exception for court orders. The new exceptions apply to:

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[62] Before a Federal savings association declares a dividend, it must send a notice, or application for approval, of the action to the Office of the Comptroller of the Currency (OCC). Whether OCC approval is required or a mere notice will suffice depends on a number of factors. For example, an application for approval is required if the proposed declaration (together with all other capital distributions) for the applicable calendar year exceeds the savings association's net income for the current year plus the retained net income for the 2 preceding years. A national bank must obtain OCC approval to declare a dividend if the total amount of all common and preferred dividends, including the proposed dividend, declared in any current year exceeds the total of the national bank's net income of the current year to date, combined with the retained net income of the previous 2 years. 12 U.S.C. 60(b).

(a) Equities mandated to be redeemed or retired by a final order of a court of competent jurisdiction;

(b) Equities held by the estate of a deceased former borrower; and

(c) Equities required by the institution to cancel under § 615.5290 in connection with a restructuring under part 617 of this chapter.

We are adding the exception for a final court order because an institution generally cannot disobey a court order. We are adding the exception for estates of former borrowers for the convenience of the estate administrator. The exception for a loan default or restructuring is limited to the required cancellation of equities under § 615.5290 and is the only offset that institutions are required to make. The other offset provisions in our regulations are permissive, not mandatory. We note that these excepted redemptions and revolvements will count in the total amount of cash payments an institution may make under the safe harbor. For payments in excess of the safe harbor cap, institutions will have to make a request to the FCA for prior approval.

We are adopting the prior approval requirements with the modifications described, including revising the reference to the minimum CET1 retention period to 7 years.

B. Regulatory Adjustments and Deductions

1. Regulatory Deductions From CET1 Capital

In the final rule, a System institution must deduct from CET1 capital the items described in § 628.22 of the proposed rule. A System institution must also exclude these deductions from its total risk weighted assets and leverage exposure. These deductions are:

a. Goodwill and Other Intangibles (Other Than Mortgage Servicing Assets)

Consistent with Basel III and the Federal regulatory banking agencies' rules, the proposed rule excluded goodwill and other intangible assets from regulatory capital because of the uncertainty that a System institution may realize value from these assets under adverse financial conditions. An institution was required to deduct goodwill and "non-mortgage" servicing assets, net of associated deferred tax liabilities (DTLs), from CET1 capital. That portion of mortgage servicing assets (MSAs) and DTAs above the threshold deductions were not risk weighted at 250 percent. Instead, the full amounts of MSAs and DTAs that arise from temporary differences relating to net operating loss carrybacks were risk weighted at 100 percent. Should the levels of MSAs held by System institutions increase significantly in the future, the FCA stated it would reconsider the appropriateness of this treatment.

The FCA did not propose the threshold deduction in Basel III and the U.S. rule for investments in other financial institutions. Instead, the proposed rule required that System institutions deduct their investments in other System institutions from their regulatory capital, as described below. Other equity investments were risk weighted according to § 628.52.

We stated that we did not believe DTAs that are risk weighted in this section would represent material items on a System institution's balance sheet because of System institutions' tax status. The FCBs and FLCAs[63] are exempt from Federal, state, municipal, and local taxation.[64] Most other System institutions' net income arises from both non-taxable and taxable sources. The production and cooperative lending business lines are taxable, but the taxable retail operations of CoBank, ACB and taxable System associations may reduce taxes by following subchapter T provisions of the Internal Revenue Code. Should the levels of DTAs held by System institutions increase significantly in the future, we stated we would reconsider the appropriateness of this proposed treatment.

The System Comment Letter agreed with the FCA that the creation or purchase of MSAs is minimal and not material in the System. The System supported our proposal not to follow what it called the more complex and irrelevant Basel III deduction approach.

The FCA has decided to finalize the goodwill, other intangibles, and MSA treatment as proposed.

b. Gain-on-Sale Associated With a Securitization Exposure

The proposed rule required a System institution to deduct from CET1 capital any after-tax gain-on-sale associated with a securitization exposure. Under GAAP, any gain-on-sale from a traditional securitization would increase a System institution's CET1 capital. However, if a System institution received cash from the sale of the securitization exposure and the MSA, it did not deduct such amount from its CET1 capital. Any sale of loans to a securitization structure that creates a gain may include an MSA that also meets the proposed definition of "gain-on-sale." A System institution must exclude any portion of a gain-on-sale reported as an MSA on FCA's Call Report.

The FCA did not receive comments on the proposed rule and is adopting it without modification.

c. Defined Benefit Pension Fund Net Assets

The proposed rule required a System institution to deduct from CET1 capital a defined benefit pension fund net asset (an overfunded pension), net of any associated DTLs, because of the uncertainty of realizing any of the value from such assets. The proposed rule recognized under GAAP the amount of a defined benefit pension fund liabilities (an underfunded pension) on the balance sheet of the institution, would be the same amount included as CET1 capital. Therefore, a System institution could not increase its CET1 capital by the derecognition of these defined pension fund liabilities.

Because existing FCA regulations do not require the deduction of the defined benefit pension fund net assets in the regulatory capital calculations, our call report does not collect defined benefit pension fund net assets. In the proposed rule preamble, we stated that we would develop a call report schedule and require each System institution to report its individual year-end transactions for defined benefit pension fund net assets on their individual call report schedule.

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[63] FLCAs are Federal land bank associations with direct long-term real estate lending authority. 12 CFR 619.9155.

[64] They are subject to taxes on real estate held to the same extent, according to its value, as other similar property held by other persons is taxed. *See* 12 U.S.C. 2023 and 2098.

The System Comment Letter objected to the proposed deduction in § 628.22(a)(5) of defined benefit pension fund net assets. The System stated that the FDIC has determined that it has access to commercial banks' prepaid pension assets in a receivership and, in the opinion of the System, the Farm Credit System Insurance Corporation (FCSIC) has authority to make the same determination.

It is the FCA's position that the FCSIC as receiver would be able to make such a determination; however, this is an authority not expressly granted in our regulations. The absence of express authority could lead to legal challenges to the receiver's access to the prepaid pension fund assets. We have decided to retain the deduction requirement at this time.

We note that the proposed rule preamble stated that we were proposing to permit an institution, with our prior approval, to risk-weight defined benefit pension fund net assets to which the institution had unfettered and unrestricted access.[65] However, this provision was not in the text of the proposed rule. In the final rule we have added it to the text. If an institution receives FCA approval to risk-weight the asset, it must risk-weight it as if it directly holds a proportional ownership share of each exposure in the defined benefit pension fund. For example, assume that: (1) The institution has a defined benefit pension fund net asset of $10; and (2) the institution has unfettered and unrestricted access to the assets of the defined benefit pension fund. Also, assume that 20 percent of the defined benefit pension fund is risk weighted at 100 percent and 80 percent is risk weighted at 300 percent. The institution must risk weight $2 at 100 percent and $8 at 300 percent. This treatment is consistent with the full look-through approach described in § 628.53(b) of the final rule.

d. A System Institution's Allocated Equity Investment in Another System Institution

Section 628.22(a)(6) of the proposed rule would have required a System institution to deduct any allocated equity investment in another System institution[66] from its CET1 capital. Later in this preamble, we discuss deducting a System institution's purchased investment in another System institution using the corresponding deduction approach in § 628.22(c).

The proposed rule had a different equity elimination method from the U.S. rule. Our method was more conservative than the Federal banking regulatory agencies' rules but consistent with the principles of Basel III and more appropriate for System institutions. It was also simpler to calculate. System associations, as member-borrowers of a cooperative network, have equity investments in their affiliated banks. System institutions also have equity investments in other System institutions but few outside the System. The investments that System institutions have in other System institutions are counted in their GAAP financial statements as equity of the issuing or allocating institution and as assets of the recipient institution. The FCA continues to believe, as we have stated numerous times previously, that equities should be counted in the regulatory capital of the institution that has control of the equities. The allocating institutions alone have discretion whether to allocate equities and when, if ever, to distribute those equities. Therefore, in the proposed rule the allocating institutions would include in their CET1 capital the equities they have allocated to their members, provided those equities meet the criteria for inclusion in CET1 capital. The institutions that have received allocated equities from other institutions would deduct those equities from their CET1 capital.

We noted that System institutions would be able to include allocated equities in CET1 capital that are excluded from core surplus under our existing regulations. These deductions applied only to investments in other System institutions because, for the most part, our investment regulations restrict equity investments outside the System.

The System Comment Letter asserted that the regulatory deductions in paragraphs (a) and (c) in new § 628.22 "ignore statutory provisions pertaining to permanent capital." The System stated its opinion that all equities categorized as tier 1 or tier 2 in the new rule must also qualify as permanent capital and must respect the allotment agreements set forth in section 4.3A(a)(1)(B). The System asserted that failure to respect the allotment agreements would have "an immediate and significant negative impact on regulatory capital ratios for some System institutions." The System requested that, because of such impact, we permit institutions to use the allotment agreements in their tier 1 and tier 2 capital ratios calculations for the next 5 years instead of the deductions in paragraph (a)(6) of § 628.22. The System said that this phase-in period would allow System banks and their affiliated associations time "to adjust allocated investments to comport with the requirements."

The FCA disagrees with the System's apparent position that the allotment agreements in section 4.3A(a)(1)(B) of the Act must be reflected in all regulatory capital calculations, as well as the implication that no other deductions or adjustments may be made to regulatory capital ratios unless they are specified in section 4.3A of the Act.[67] All of our capital regulations since the enactment of the 1987 amendments to the Act[68] have contained eliminations of both purchased and allocated equities, as well as deductions and adjustments for such items as goodwill, that are not mentioned in the Act. Since 1997, under our statutory authority in section 4.3(a) of the Act, our capital regulations have included a core surplus ratio whose deductions and adjustments do not reflect the allotment agreements. As for the new tier 1 and tier 2 regulatory capital ratios, it is our judgment that the deductions and adjustments in § 628.22 more appropriately categorize the control of shared capital as within the discretion of the institution that allocated the equities and not the recipient institution. As stated in the preamble to the proposed rule, we strongly believe that the deductions and adjustments for the CET1 capital ratio calculation appropriately reflect that the allocated equities are within the control of, and subject to the risks in, the allocating institution and not the recipient institution. Moreover, we believe the deductions and adjustments are consistent with the intent of the Basel III framework and the U.S. rule.

Currently a small number of associations with large allocations of equities from their affiliated banks count a large portion of those equities in their permanent capital ratio calculations. The associations will, of course, be able to continue to make allotment agreements for the permanent capital ratio calculations when the new rule becomes final. Our projections of System institutions' initial compliance with the tier 1 and tier 2 capital requirements are discussed below in Section VII of this preamble. Those projections show that these associations' CET1 capital ratios are likely to be lower than they would have been if the calculations had included the allotment agreements. However, we do not expect the "lower" CET1 capital ratios to have a significant negative impact on those associations. Consequently, we have decided not to adopt a phase-in period for the deductions and adjustments.

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[65] *See* 79 FR 52828 (September 4, 2014).

[66] An example would be an association's equity investment in its System bank.

[67] We observe that, in including up to 1.25 percent of ALL in tier 2 consistent with the Basel III framework and the U.S. rule, we are squarely deviating from the permanent capital ratio calculation because ALL is expressly excluded from the definition of permanent capital in section 4.3A(a)(1)(C).

[68] Agricultural Credit Act of 1987, Pub. L. 100–233, 101 Stat. 1568 (100th Cong.), January 6, 1988.

We are adopting the § 628.22(a)(6) deduction of allocated equity investments without modification from the proposed rule.

e. Accumulated Other Comprehensive Income (AOCI) and Minority Interests

We stated in the preamble to our proposed rule that we proposed not to include the impacts of AOCI on CET1 capital. We did not receive any comments on the proposal, and this treatment is unchanged in the final rule. As we discussed in detail in the proposed rule preamble, our treatment is different from Basel III and the U.S. rule, which require banking organizations to include most elements of AOCI in CET1.[69] However, the U.S. rule permits banking organizations using the standardized approach to make a one-time election not to exclude most elements of AOCI in their regulatory capital. Under the FCA's AOCI treatment, the exclusion of AOCI from CET1 capital is comparable to the AOCI exclusions of the banking organizations that make an election not to include AOCI in their CET1 capital.

Our proposed rule did not include minority interests in CET1 and any other component of regulatory capital because System institutions have few or no minority equity interests in unconsolidated subsidiaries. This treatment is unchanged in the final rule.

f. Discretionary "Haircut" Deduction or Other FCA Supervisory Action for Redemption of Equities Included in CET1 Capital Less Than 7 Years After Issuance or Allocation

Under § 628.22(f) of the proposed rule, if a System institution redeemed or revolved CET1 equities prior to the applicable minimum revolvement period, the institution was required to exclude 30 percent of the remaining purchased and allocated equities otherwise includable in CET1 capital for 3 years (30-percent haircut).

The System Comment Letter objected to the proposed haircut as an entirely new concept, not found in Basel III or regulations of other regulators, illogical from a policy perspective, and unclear. The System, among other criticisms, stated that a recordkeeping error or other de minimis redemptions could result in the required deduction, and that it was unclear whether the deduction was meant to be applied one time only or was cumulative or overlapping for repeated violations. The System suggested that the haircut could be a standing deduction to CET1 rather than a haircut for a violation. It is unclear to us what this suggestion means, other than perhaps, in effect, to allow institutions to apply a 30-percent haircut to their CET1 in order to eliminate the 7-year minimum redemption and revolvement period.

The FCA intended the 30-percent haircut to ensure proper management by System institutions of their member-borrowers' expectations of redemption and also to ensure that institutions are vigilant in their recordkeeping of the issuance and allocation dates of CET1. We continue to consider accurate recordkeeping to be very important under the new rule. However, in response to the comments, we have reconsidered the mandatory deduction and decided to revise it. Instead of a mandatory deduction, we have decided to identify the deduction of a portion of equities from CET1 as one of a possible range of supervisory or enforcement actions the FCA could take in response to a violation of the minimum redemption and revolvement period. Should we ever impose a haircut, we will specify the precise percentage and duration and whether the haircut could be cumulative or overlapping for repeated violations.

The final rule states that the FCA may respond to an institution's redemption or revolvement in violation of the minimum holding period by requiring such a haircut deduction or by taking other appropriate supervisory or enforcement action.

2. The Corresponding Deduction Approach for Purchased Equities

Section 628.22(c) incorporated the Basel III corresponding deduction approach for a System institution's purchased equity investment in another System institution. The corresponding deduction approach did not apply to allocated equity investments in another System institution. We responded above, in Section III.B.1.d under "Regulatory Adjustments and Deductions," to the System Comment Letter's objections to the deductions of both purchased and allocated investments in other System institutions.

Under the final rule, a System institution is required to deduct an amount from the same component of capital for which the underlying instrument would qualify as if the System institution had issued the instrument itself. If a System institution does not have a sufficient amount of the specific component of regulatory capital for the entire deduction, then it must deduct the remaining portion from the next higher (more subordinated) capital component. Should a System institution not have enough AT1 capital to satisfy the required deduction, the shortfall must be deducted from CET1 capital elements.

Other than as described above, we did not receive comments on the corresponding deduction approach in the proposed rule and adopt the provision without modification.

3. Netting of Deferred Tax Liabilities Against Deferred Tax Assets and Other Deductible Assets

In the proposed rule, the FCA proposed to simplify the netting of DTLs against DTAs and other deductible assets for deductions of DTAs. The proposal differed from the U.S. rule for deductions of DTAs. Rather, System institutions were required to adjust CET1 capital under § 628.22(a) net of any associated deferred tax effects. In addition, System institutions were required to deduct from CET1 capital elements under § 628.22(a) and (c) of the rule net of associated DTLs, pursuant to § 628.22(e). There is a detailed discussion of the proposal in the preamble to the proposed rule.[70]

We did not receive any comments on this proposed provision and adopt it without modifications.

C. Limits on Inclusion of Third-Party Capital

In the final rule, we continue to impose limits on the inclusion of third-party capital. However, in response to comments, in the final rule we have revised the limitations on third-party capital that we proposed. Specifically, third-party capital allowed to be included in total capital is limited to the lesser of 40 percent of total capital or 100 percent of common-equity tier 1. The final rule does not include separate limits on tier 1 capital and total capital; rather, there is one overall limit based on the aforementioned factors. However, if other capital instruments, such as unallocated retained earnings or common cooperative equities, decline in subsequent quarters causing third-party capital to exceed limits set in this final rule, an institution would still be able to include its existing level of third-party capital in its regulatory capital ratios. This limit increases the amount of third-party capital allowed in tier 1 from the proposed rule by up to 100 percent. A System institution could include third-party capital in tier 1 up to a level nearly equal to common-equity tier 1 or 40 percent of total capital, whichever is less. In the proposed rule, third-party capital allowed in tier 1 was equal to 33 percent of common-equity tier 1. We have substantially increased the amount of third-party capital allowed in tier 1 to provide member-borrowers increased flexibility to manage the affairs of their institution, which include prudent capital planning and management. The amount of third-party capital allowed in total capital is substantially similar to that of the proposed rule (40 percent of total capital); however, we have removed the limit of an amount equal to 100 percent of its tier 1 capital outstanding. We believe it is appropriate to remove this limit given the substantial increase of third-party capital allowed to be included in tier 1 capital. Furthermore, removal of this limit would not result in a reduction of third-party capital a System institution could include in total capital.[71] The calculations for all limits will be based on the previous four quarters to ensure stability of the calculation and reduce the volatility associated with changes in total capital and common equity tier 1 amounts.

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[69] *See* 79 FR 52825.

[70] *See* 79 FR 52829–52830.

As previously stated, FCA believes it is prudent to set a limit on the amount of third-party capital a System institution includes in its regulatory capital ratios. This limit ensures that unallocated retained earnings and common cooperative equities are the dominant forms of capital in the System and that the cooperative principal of user-control is not undermined. This increased limit provides increased flexibility for System institutions to manage its capital while ensuring that its member-borrowers' decisions are not heavily influenced by meeting third-party capital obligations. Commenters asserted that the applicable cooperative principle is user-benefit, and we believe that the limits do not undermine this principle.

The formulas for calculating third-party capital limits are:

$$1.\ CLTPC = min\left[\left(\sum_{n=1}^{4} \frac{(T1_n - NPPS_n)}{4}\right),\ 2/3\left(\sum_{n=1}^{4} \frac{(TC_n - TPC_n)}{4}\right)\right]$$

where

CLTPC = current limit on all third-party capital (noncumulative perpetual preferred stock, term preferred stock, and subordinated debt) in total capital, calculated this quarter,

T1 = tier 1 capital,

NPPS = noncumulative perpetual preferred stock included in tier 1 capital,

TC = total capital (tier 1 capital + tier 2 capital), and

TPC = third-party capital included in total capital, and

n = 4 previous quarters, 1–4

2. ALTPC = max(ELTPC,CLTPC)

where

ALTPC = Aggregate limit on third-party capital,

ELTPC = existing limit on all third-party capital (noncumulative perpetual preferred stock, term preferred stock, and subordinated debt) in total capital, calculated the previous quarter,

CLTPC = current limit on all third-party capital (noncumulative perpetual preferred stock, term preferred stock, and subordinated debt) in total capital, calculated this quarter.

IV. Standardized Approach for Risk Weighted Assets

A. Calculation of Standardized Total Risk Weighted Assets

In general, commenters stated that they believed the risk weights we proposed were consistent with the implementation of Basel III by U.S. and foreign banking regulators, and they did not identify concerns with most of these risk weights. Commenters did request changes to or clarifications of several proposed risk-weighting provisions, however. We discuss those comments, and explain our response, in our discussion of those provisions. All provisions are generally adopted as proposed, unless a change is discussed.[72]

In addition to the revisions discussed below, we also adopt definitions of "qualifying master netting agreement," "collateral agreement," "eligible margin loan," and "repo-style transaction" that are revised from what we proposed. The OCC and the Federal Reserve Board adopted similar revisions to these terms after they adopted their capital rules.[73] These revisions are designed to ensure that the regulatory treatment of certain financial contracts is not affected by implementation of special resolution regimes in foreign jurisdictions or by the International Swaps and Derivatives Association Resolution Stay Protocol.

Similar to the FCA's current risk-based capital rules, under these new rules a System institution must calculate its total risk weighted assets by adding together its on- and off-balance sheet risk weighted asset amounts and making any relevant adjustments to incorporate required capital deductions.[74] Risk weighted asset amounts generally are determined by assigning on-balance sheet assets to broad risk-weight categories according to the asset type, the counterparty or, if relevant, the guarantor or collateral. Similarly, risk weighted asset amounts for off-balance sheet items are calculated using a two-step process: (1) Multiplying the amount of the off-balance sheet exposure[75] by a CCF to determine a credit equivalent amount; and (2) assigning the credit equivalent amount to a relevant risk-weight category.

A System institution must determine its standardized total risk weighted assets by calculating the sum of its risk weighted assets for general credit risk, cleared transactions, unsettled transactions, securitization exposures, and equity exposures, each as defined below, less the System institution's allowance for loan losses (ALL) that is not included in tier 2 capital (as described in § 628.20 of the rule). The sections below describe in more detail how a System institution must determine the risk weighted asset amounts for its exposures.

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[71] In the proposed rule, third-party capital allowed in total capital was limited to the *lesser* of: 40 percent of total capital or 100 percent of tier 1 capital outstanding. FCA believes that the limiting factor in almost all cases will be the 40 percent of total capital limit. Given the System's current capital composition, the majority of capital instruments are tier 1 instruments. In order for 100 percent of tier 1 to be lower than 40 percent of total capital, System institutions would need to substantially decrease tier 1 instruments and substantially increase tier 2 instruments. As the regulatory minimum ratios (including capital conservation buffer) are 8 percent for tier 1 and 10.5 percent for total capital, as well as the leverage ratio is based on tier 1 capital, the FCA believes it is unlikely that 100 percent of tier 1 capital will ever be lower than 40 percent of total capital.

[72] We do not discuss changes from the proposed rule that are minor, technical, and nonsubstantive.

[73] Interim final rule with request for comment, 79 FR 78287, December 30, 2014. The FDIC has proposed similar revisions, 80 FR 5063, January 30, 2015, but has not finalized them.

[74] *See generally* the FCA's regulations at part 615, subpart H.

[75] The term "exposure," which is defined as an amount at risk, is used throughout the final rule and preamble.

B. Risk Weighted Assets for General Credit Risk

Under the final rule, total risk weighted assets for general credit risk is the sum of the risk weighted asset amounts as calculated under § 628.31(a) of the rule. General credit risk exposures include a System institution's on-balance sheet exposures (other than cleared transactions, securitization exposures, and equity exposures, each as defined in § 628.2 of the final rule), exposures to over-the-counter (OTC) derivative contracts, off-balance sheet commitments, trade and transaction-related contingencies, guarantees, repo-style transactions, financial standby letters of credit, forward agreements, or other similar transactions. Section 628.32 of the final rule describes the risk weights that apply to sovereign exposures; exposures to certain supranational entities and multilateral development banks (MDBs); exposures to Government-sponsored enterprises (GSEs); exposures to depository institutions, foreign banks, and credit unions (including certain exposures to other financing institutions (OFIs) owned or controlled by these entities); exposures to public sector entities (PSEs); corporate exposures (including certain exposures to OFIs); residential mortgage exposures; past due and nonaccrual exposures; and other assets (including cash, gold bullion, and certain MSAs and DTAs).

Generally, the exposure amount for the on-balance sheet component of an exposure is the System institution's carrying value for the exposure as determined under generally accepted accounting principles (GAAP). Because all System institutions use GAAP to prepare their financial statements, we believe that using GAAP to determine the amount and nature of an exposure provides a consistent framework that System institutions can easily apply.

For purposes of the definition of exposure amount for available-for-sale (AFS) or held-to-maturity (HTM) debt securities and AFS preferred stock not classified as equity under GAAP, the exposure amount is the System institution's carrying value (including net accrued but unpaid interest and fees) for the exposure, less any net unrealized gains, and plus any net unrealized losses. For purposes of the definition of exposure amount for AFS preferred stock classified as an equity security under GAAP, the exposure amount is the System institution's carrying value (including net accrued but unpaid interest and fees) for the exposure, less any net unrealized gains that are reflected in such carrying value but excluded from the System institution's regulatory capital.[76]

In most cases, the exposure amount for an off-balance sheet component of an exposure would typically be determined by multiplying the notional amount of the off-balance sheet component by the appropriate CCF as determined under § 628.33 of the final rule. The exposure amount for an OTC derivative contract or cleared transaction that is a derivative would be determined under § 628.34 of the final rule, whereas exposure amounts for collateralized OTC derivative contracts, collateralized cleared transactions that are derivatives, repo-style transactions, and eligible margin loans would be determined under § 628.37 of the final rule.

1. Exposures to Sovereigns

Under the final rule, a sovereign is defined as a central government (including the U.S. Government) or an agency, department, ministry, or central bank of a central government (for the U.S. Government, the central bank is the Federal Reserve). The final rule retains the current rules' risk weights for exposures to and claims directly and unconditionally guaranteed by the U.S. Government or its agencies.[77] Accordingly, exposures to the U.S. Government, the Federal Reserve, or a U.S. Government agency, and the portion of an exposure that is directly and unconditionally guaranteed by the U.S. Government, the Federal Reserve, or a U.S. Government agency receive a 0-percent risk weight.[78] Consistent with the current risk-based capital rules, the portion of a deposit insured by the Federal Deposit Insurance Corporation (FDIC) or the National Credit Union Administration (NCUA) is also assigned a 0-percent risk weight.

An exposure conditionally guaranteed by the U.S. Government, the Federal Reserve, or a U.S. Government agency receives a 20-percent risk weight. This includes an exposure that is conditionally guaranteed by the FDIC or the NCUA.[79]

The FCA's existing risk-based capital rules generally assign risk weights to direct exposures to sovereigns and exposures directly guaranteed by sovereigns based on whether the sovereign is a member of the Organization for Economic Cooperation and Development (OECD) and, as applicable, whether the exposure is unconditionally or conditionally guaranteed by the sovereign.[80]

The OECD assigns Country Risk Classifications (CRCs) to many countries as an assessment of their credit risk. CRCs are used to set interest rate charges for transactions covered by the OECD arrangement on export credits. The OECD uses a scale of 0 to 7 with 0 being the lowest possible risk and 7 being the highest possible risk. The OECD no longer assigns CRCs to certain high-income countries that are members of the OECD and that have previously received a CRC of 0. These countries exhibit a similar degree of country risk as that of a jurisdiction with a CRC of 0.[81]

Under the final rule, the risk weight for exposures to countries with CRCs is determined based on the CRCs. Exposures to OECD member countries that do not have CRCs are risk weighted at 0 percent. Exposures to non-OECD members with no CRC are risk weighted at 100 percent.[82] The OECD regularly updates CRCs and makes the assessments publicly available on its Web site. Accordingly, the FCA believes that the CRC approach should not represent undue burden to System institutions.

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[76] Although System banks often classify their securities as AFS, associations almost always classify their securities, to the extent they hold any, as HTM.

[77] A U.S. Government agency is defined under the final rule as an instrumentality of the U.S. Government whose obligations are fully guaranteed as to the timely payment of principal and interest by the full faith and credit of the U.S. Government.

[78] Similar to the FCA's current risk-based capital rules, a claim is not considered unconditionally guaranteed by a central government if the validity of the guarantee is dependent upon some affirmative action by the holder or a third party.

[79] Because of the issues such an exposure would raise, the FCA will determine the risk-weight of any System institution exposure that has a FCSIC guarantee, whether conditional or unconditional, on a case-by-case basis.

[80] Section 615.5211.

[81] For more information on the OECD country risk classification methodology, *see generally* OECD, "Country Risk Classification," available at *http://www.oecd.org/tad/xcred/crc.htm.*

[82] This final rule, like the U.S. rule, permits a lower risk weighting for sovereign exposures if certain conditions are met, including that the exposure is denominated in the sovereign's currency. Although the investment eligibility regulation applicable to System institutions require that all investments must be denominated in U.S. dollars (*see* § 615.5140(a) of our regulations), this lower risk weight could be used if a System institution were to foreclose on collateral in the form of such a sovereign exposure.

The FCA believes that use of CRCs in the final rule is permissible under section 939A of the Dodd-Frank Act and that section 939A was not intended to apply to assessments of creditworthiness by organizations such as the OECD. Section 939A is part of subtitle C of title IX of the Dodd-Frank Act, which, among other things, enhances regulation by the U.S. Securities and Exchange Commission (SEC) of credit rating agencies, including Nationally Recognized Statistical Rating Organizations (NRSROs) registered with the SEC. Section 939A requires agencies to remove references to credit ratings and NRSROs from Federal regulations. In the introductory "findings" section to subtitle C, which is entitled "Improvements to the Regulation of Credit Ratings Agencies," Congress characterized credit rating agencies as organizations that play a critical "gatekeeper" role in the debt markets and perform evaluative and analytical services on behalf of clients, and whose activities are fundamentally commercial in character.[83] Furthermore, the legislative history of section 939A focuses on the conflicts of interest of credit rating agencies in providing credit ratings to their clients, and the problem of government "sanctioning" of the credit rating agencies' credit ratings by having them incorporated into Federal regulations. The OECD is not a commercial entity that produces credit assessments for fee-paying clients, nor does it provide the sort of evaluative and analytical services as credit rating agencies.

Additionally, the FCA notes that the use of the CRCs is limited in the rule. The FCA considers CRCs to be a reasonable alternative to credit ratings for sovereign exposures and the proposed CRC methodology to be more granular and risk sensitive than the current risk-weighting methodology based solely on OECD membership.

The final rule also requires a System institution to apply a 150-percent risk weight to sovereign exposures immediately upon determining that an event of sovereign default has occurred or if an event of sovereign default has occurred during the previous 5 years. Sovereign default is defined in the final rule as a noncompliance by a sovereign with its external debt service obligations or the inability or unwillingness of a sovereign government to service an existing loan according to its original terms, as evidenced by failure to pay principal or interest fully and on a timely basis, arrearages, or restructuring. A default includes a voluntary or involuntary restructuring that results in a sovereign not servicing an existing obligation in accordance with the obligation's original terms.

TABLE 3—RISK WEIGHTS FOR SOVEREIGN EXPOSURES

	Risk weight (in percent)
CRC:	
0–1	0
2	20
3	50
4–6	100
7	150
OECD Member with No CRC	0
Non-OECD Member with No CRC	100
Sovereign Default	150

2. Exposures to Certain Supranational Entities and Multilateral Development Banks

Under the FCA's existing risk-based capital rules, exposures to certain supranational entities and multilateral development banks (MDBs) receive a 20-percent risk weight. Consistent with the Basel framework's treatment of exposures to supranational entities, the FCA's final rule applies a 0-percent risk weight to exposures to the Bank for International Settlements, the European Central Bank, the European Commission, and the International Monetary Fund.

Similarly, the final rule applies a 0-percent risk weight to exposures to an MDB. The rule defines an MDB to include the International Bank for Reconstruction and Development, the Multilateral Investment Guarantee Agency, the International Finance Corporation, the Inter-American Development Bank, the Asian Development Bank, the African Development Bank, the European Bank for Reconstruction and Development, the European Investment Bank, the European Investment Fund, the Nordic Investment Bank, the Caribbean Development Bank, the Islamic Development Bank, the Council of Europe Development Bank, and any other multilateral lending institution or regional development bank in which the U.S. Government is a shareholder or contributing member or which the FCA determines poses comparable credit risk.

The FCA believes this treatment is appropriate in light of the generally high credit quality of MDBs, their strong shareholder support, and a shareholder structure comprised of a significant proportion of sovereign entities with strong creditworthiness. Exposures to regional development banks and multilateral lending institutions that are not covered under the definition of MDB generally are treated as corporate exposures and receive a 100-percent risk weight.

3. Exposures to Government-Sponsored Enterprises

Like the Federal banking regulatory agencies, we define GSE as an entity established or chartered by the U.S. Government to serve public purposes specified by the U.S. Congress but whose debt obligations are not explicitly guaranteed by the full faith and credit of the U.S. Government. Because we believed it would make the regulations somewhat simpler, our proposed rule had excluded System institutions from this definition for the purpose of these capital rules.

The System is, however, a GSE, and the System Comment Letter asserted that our proposed definition was fundamentally incorrect and subject to misinterpretation. To alleviate any concerns about possible confusion regarding the System's GSE status, the final rule eliminates this exclusion. Accordingly, under our final rule, as under the U.S. rule, GSEs include the Federal National Mortgage Association (Fannie Mae), the Federal Home Loan Mortgage Corporation (Freddie Mac), the System, the Federal Home Loan Bank System, and Farmer Mac.[84]

The final rule assigns a 20-percent risk weight to exposures to GSEs that are not equity exposures or preferred stock; this includes loans from System banks to associations (direct loans).[85]

The final rule assigns a 100-percent risk weight to preferred stock issued by a non-System GSE. This risk weighting represents a change to the FCA's existing risk-based capital rules, which currently allow a System institution to apply a 20-percent risk weight to GSE preferred stock.[86]

Under final § 628.22, a System institution must deduct from regulatory capital all equity investments (including preferred stock) in another System institution, and therefore we do not provide a risk weighting for these investments. These investments could include, for example, an association's investment in a System bank and a System bank's investment in an association.[87]

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[83] *See* Dodd-Frank Act, section 931 (15 U.S.C. 78o–7 note).

[84] As discussed above, Farmer Mac is an institution of the System, but because this regulation does not apply to Farmer Mac, it is not included in references to the System or System institutions in this regulation or preamble.

[85] Because System institutions were not included within the proposed rule's definition of GSE, the proposed rule explicitly assigned a 20-percent risk weight to System bank loans to associations. In the final rule, these loans are included generally within the provision assigning a 20-percent risk weight to exposures to GSEs.

[86] Section 615.5211(b)(6).

System institutions have the authority to enter into loss-sharing agreements with other System institutions under § 614.4340. If System institutions enter into a loss-sharing agreement in the future, the FCA would assign a risk weight for any associated exposures at that time, using our regulatory reservation of authority.

4. Exposures to Depository Institutions, Foreign Banks, and Credit Unions

The FCA's existing risk-based capital rules assign a 20-percent risk weight to all exposures to U.S. depository institutions and foreign banks incorporated in an OECD country. Short-term exposures to foreign banks incorporated in a non-OECD country receive a 20-percent risk weight and long-term exposures to such entities receive a 100-percent risk weight.

Under the final rule, exposures to U.S. depository institutions and credit unions are assigned a 20-percent risk weight.[88] This risk weight applies to a System bank exposure to an OFI that is owned and controlled by a U.S. or state depository institution or credit union that guarantees the exposure. If the OFI exposure does not satisfy these requirements, it is assigned a 50-percent or 100-percent risk weight as a corporate exposure pursuant to § 628.32(f).

Our existing OFI rules assign a 20-percent risk weight to a claim on an OFI that is an OECD bank or is owned and controlled by an OECD bank that guarantees the claim or if the OFI or its parent has a sufficiently high credit rating.[89] This final rule imposes the same risk weight for OFI exposures of the same nature, except that we eliminate the credit rating alternative in accordance with section 939A of the Dodd-Frank Act.

Under this final rule, an exposure to a foreign bank receives a risk weight one category higher than the risk weight assigned to a direct exposure to the foreign bank's home country, based on the assignment of risk weights by CRC, as discussed above.[90] Exposures to a foreign bank in a country that does not have a CRC but that is a member of the OECD receive a 20-percent risk weight. A System institution must assign a 100-percent risk weight to an exposure to a foreign bank in a non-OECD member country that does not have a CRC, except that the institution may assign a 20-percent risk weight to self-liquidating, trade-related contingent items that arise from the movement of goods and that have a maturity of 3 months or less.

A System institution must assign a 150-percent risk weight to an exposure to a foreign bank immediately upon determining that an event of sovereign default has occurred in the bank's home country, or if an event of sovereign default has occurred in the foreign bank's home country during the previous 5 years.

TABLE 4—RISK WEIGHTS FOR EXPOSURES TO FOREIGN BANKS

	Risk weight
Sovereign CRC:	
0–1	20
2	50
3	100
4–7	150
OECD Member with no CRC	20
Non-OECD Member with no CRC	100
Sovereign Default	150

Both the Basel capital framework and our existing regulation treat exposures to securities firms that meet certain requirements like exposures to depository institutions.[91] However, like the Federal banking regulatory agencies, the FCA no longer believes that the risk profile of these firms is sufficiently similar to depository institutions to justify that treatment. Accordingly, the final rule requires System institutions to treat exposures to securities firms as corporate exposures, with a 100-percent risk weight.

5. Exposures to Public Sector Entities

The FCA's existing risk-based capital rules assign a 20-percent risk weight to general obligations of states and other political subdivisions of OECD countries.[92] Exposures that rely on repayment from specific projects (for example, revenue bonds) are assigned a risk weight of 50 percent. Other exposures to state and political subdivisions of OECD countries (including industrial revenue bonds) and exposures to political subdivisions of non-OECD countries receive a risk weight of 100 percent. The risk weights assigned to revenue obligations are higher than the risk weight assigned to general obligations because repayment of revenue obligations depends on specific projects, which present more risk relative to a general repayment obligation of a state or political subdivision of a sovereign.

The final rule applies the same risk weights to exposures to U.S. states and municipalities as the existing risk-based capital rules apply. Under the final rule, these political subdivisions are included in the definition of "public sector entity" (PSE). Consistent with both the current rules and the Basel capital framework, the final rule defines a PSE as a state, local authority, or other governmental subdivision below the level of a sovereign. This definition includes U.S. states and municipalities and does not include government-owned commercial companies that engage in activities involving trade, commerce, or profit that are generally conducted or performed in the private sector.

Under the final rule, a System institution would assign a 20-percent risk weight to a general obligation exposure to a PSE that is organized under the laws of the United States or any state or political subdivision thereof and a 50-percent risk weight to a revenue obligation exposure to such a PSE. The final rule defines a general obligation as a bond or similar obligation that is backed by the full faith and credit of a PSE. The final rule defines a revenue obligation as a bond or similar obligation that is an obligation of a PSE, but which the PSE is committed to repay with revenues from a specific project financed rather than general tax funds.

Similar to the Basel framework's use of home country risk weights to assign a risk weight to a PSE exposure, the final rule requires a System institution to apply a risk weight to an exposure to a non-U.S. PSE based on (1) The CRC applicable to the PSE's home country or, if the home country has no CRC, whether it is a member of the OECD, and (2) whether the exposure is a general obligation or a revenue obligation, in accordance with Table 5.

The risk weights assigned to revenue obligations are higher than the risk weights assigned to a general obligation issued by the same PSE, as set forth, for non-U.S. PSEs, in Table 5. Similar to exposures to a foreign bank, exposures to a non-U.S. PSE in a country that does not have a CRC rating receive a 100-percent risk weight. Exposures to a non-U.S. PSE in a country that has defaulted on any outstanding sovereign exposure or that has defaulted on any sovereign exposure during the previous 5 years receive a 150-percent risk weight. Table 5 illustrates the risk weights for exposures to non-U.S. PSEs.

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[87] As discussed above, Farmer Mac's preferred stock is assigned a risk weight of 100 percent.

[88] A depository institution is defined in section 3 of the Federal Deposit Insurance Act (12 U.S.C. 1813(c)(1)). Under this final rule, a credit union refers to an insured credit union as defined under the Federal Credit Union Act (12 U.S.C. 1752(7)).

[89] Section 615.5211(b)((16).

[90] Foreign bank means a foreign bank as defined in § 211.2 of the Federal Reserve Board's Regulation K (12 CFR 211.2), that is not a depository institution. For purposes of this final rule, home country meant the country where an entity is incorporated, chartered, or similarly established.

[91] *See* § 615.5211(b)(14) and (15).

[92] Political subdivisions of the United States include states, counties, cities, towns or other municipal corporations, public authorities, and generally any publicly owned entities that are instruments of a state or municipal corporation.

TABLE 5—RISK WEIGHTS FOR EXPOSURES TO NON-U.S. PSE GENERAL OBLIGATIONS AND REVENUE OBLIGATIONS

[in percent]

	Risk weight for exposures to non-U.S. PSE general obligations	Risk weight for exposures to non-U.S. PSE revenue obligations
Sovereign CRC:		
0–1	20	50
2	50	100
3	100	100
4–7	150	150
OECD Member with No CRC	20	50
Non-OECD Member with No CRC	100	100
Sovereign Default	150	150

The final rule allows a System institution to apply a risk weight to an exposure to a non-U.S. PSE according to the risk weight that the foreign banking organization supervisor allows to be assigned to it. In no event, however, may the risk weight for an exposure to a non-U.S. PSE be lower than the risk weight assigned to direct exposures to that PSE's home country.

6. Corporate Exposures

Under the FCA's existing risk-based capital rules, credit exposures to companies that are not depository institutions or securitization vehicles generally are assigned to the 100-percent risk weight category. A 20-percent risk weight is assigned to claims on, or guaranteed by, a securities firm incorporated in an OECD country that satisfies certain conditions.

The requirements of the final rule are generally consistent with the existing risk-based capital rules and require System institutions generally to assign a 100-percent risk weight to all corporate exposures.[93] The final rule defines a corporate exposure as an exposure to a company that is not an exposure to a sovereign, the Bank for International Settlements, the European Central Bank, the European Commission, the International Monetary Fund, an MDB, a depository institution, a foreign bank, or a credit union, a PSE, a GSE, a residential mortgage exposure, a cleared transaction, a securitization exposure, an equity exposure, or an unsettled transaction. This definition captures all exposures that are not otherwise included in another specific exposure category and is not limited to exposures to corporations.

Accordingly, this category includes borrower loans such as agricultural loans and consumer loans, regardless of the corporate form of the borrower, unless those loans qualify for different risk weights (such as a 50-percent risk weight for residential mortgage exposures) under other provisions. This category also includes premises, fixed assets, and other real estate owned.

Because they are corporate exposures, we proposed to include in this category all OFI exposures that do not qualify for the 20-percent depository institution/credit union risk weight provided in § 628.32(d) and discussed above. Our existing rules also contain a default 100-percent risk weight category.[94] But our existing regulations also contain an intermediate, 50-percent risk weight category for claims on OFIs that do not satisfy the requirements for a 20-percent risk weight but that otherwise meet similar capital, risk identification and control, and operational standards or that carry an investment grade NRSRO rating.[95] Only if an OFI does not satisfy these standards does a claim on it receive a 100-percent risk weighting.

We proposed to eliminate the 50-percent risk weight for OFIs and to assign a 100-percent risk weight to exposures to non-depository institution/non-credit union OFIs. In our proposal, we noted that this 50-percent risk weighting for what would otherwise be a corporate exposure is inconsistent with our treatment of other corporate exposures. We also noted that the Federal banking regulatory agencies would assign a 100-percent risk weight to these exposures.

We sought comment on our proposed capital treatment of exposures to OFIs and specifically on our proposal to eliminate the 50-percent risk weight. We received comments on this proposal from several OFIs and in the System Comment Letter. All commenters urged us to retain the 50-percent risk weight. Moreover, the OFIs suggested that we eliminate the 100-percent risk weight entirely.

In support of their request to retain the 50-percent risk weight, the OFIs stated that OFIs have historically been instrumental to the System and deserve recognition and fairness for their historical role. They also stated that FCA's policies have always been designed to ensure that OFIs have competitive access to System bank funding and that increasing the risk weight requirements could impair this competitive access. In addition, they stated that OFI borrowing is not risky because of the System banks' underwriting standards and loan terms and conditions and because the FCA oversees the banks' relationships with their OFIs and has the authority to examine OFIs.

The System Comment Letter asserted that the current risk weight regime has worked effectively, as evidenced by the System's low loss experience on OFI loans. According to this Letter, the underwriting requirements for OFIs found in FCA regulations at subpart P of part 614, coupled with the two levels of capital that support the exposure of System banks to OFIs (capital is held at the OFI level and at the individual OFI borrower level), make a higher risk weight inappropriate. Moreover, the Letter stated that OFIs are unique to the System and the FCA's regulations are designed not to hinder these relationships.

We believe the existing approach to risk weighting OFI exposures has worked well since it was adopted in 2004. As we said at that time, when we first adopted a 50-percent risk weight for lower-risk non-depository institution/non-credit union OFI exposures:

> Lowering the capital requirements for most OFI loans will lower the operating costs of the OFI program to Farm Credit banks. This, in turn, should lower the cost of funds to well-capitalized and well-managed OFIs. Lower funding costs should enable these OFIs to reduce interest rates charged to their borrowers. These results would advance the System's public policy mission to provide affordable credit on a consistent basis to agriculture and rural America. Greater flexibility for the risk weighting of OFI loans should provide the Farm Credit banks additional incentives to expand their lending to both existing and new OFIs.[96]

These ideas continue to be true today. Accordingly, the final rule retains a 50-percent risk weight for exposures to non-depository institution/non-credit union OFIs that meet capital, risk identification and control, and operational standards similar to regulated depository institutions and credit unions. The final rule also retains a 50-percent risk weight for exposures to non-depository institution/non-credit union OFIs that are investment grade or are owned and controlled by an investment grade entity that guarantees the exposures.

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[93] For reasons discussed below, exposures to lower-risk OFIs that do not qualify for a 20-percent risk weight are assigned a 50-percent risk weight. The U.S. rule would assign a 100-percent risk weight to these exposures, because they satisfy the definition of corporate exposure and do not qualify for a different risk weight. The laws and regulations governing the banking organizations regulated by the Federal banking regulatory agencies do not contemplate the OFI relationship, as the Act does.

[94] Section 615.5211(d)(11).

[95] Section 615.5211(c)(5).

[96] 69 FR 29852, 29862, May 26, 2004.

In accordance with the Dodd-Frank Act, "investment grade" in the final rule refers to the definition in the rule rather than to NRSRO ratings. The final rule defines "investment grade," in pertinent part, to mean that the entity to which the System institution is exposed through a loan has adequate capacity to meet financial commitments for the projected life of the exposure. Such an entity has adequate capacity to meet financial commitments if the risk of its default is low and the full and timely repayment of principal and interest is expected.

We do not intend for the elimination of NRSRO ratings to change substantively the standards System institutions must follow when deciding whether an exposure is investment grade. A System institution may, but is not required to, consider NRSRO ratings as part of its independent investment grade determination and due diligence. An institution's consideration of NRSRO ratings must be supplemented by the institution's own independent analysis; an exposure does not automatically satisfy an investment grade standard by virtue of its NRSRO rating.

We decline to eliminate the 100-percent risk weight for exposures to OFIs that do not satisfy the criteria for a more favorable risk weight. The higher risk inherent in exposures to those OFIs warrants the 100-percent risk weight that is generally applicable to corporate exposures.

Finally, in contrast to the FCA's existing risk-based capital rules, all securities firms are subject to the same treatment as corporate exposures.

7. Residential Mortgage Exposures

The FCA's existing risk-based capital rules assign "qualified residential loans" to the 50-percent risk-weight category.[97] Qualified residential loans include both rural home loans authorized under § 613.3030 and single-family residential loans to bona fide farmers, ranchers, and producers and harvesters of aquatic products. Qualified residential loans must have been approved in accordance with prudent underwriting standards suitable for residential property and must not be 90 days or more past due or carried in nonaccrual status.[98] If the loan does not satisfy these safety and soundness standards, or the property is not characteristic of residential property, the loan receives a 100-percent risk weight.

In general, although our existing rule is structured differently, our existing safety and soundness standards are very similar to the U.S. rule's risk-weighting requirements for residential mortgage exposures.[99] The major differences between the two sets of rules are the FCA's criteria regarding the characteristics of residential property, which the U.S. rule does not have.

In the interest of consistency, we now structure our final rule the same way as the Federal banking regulatory agencies do. Moreover, we adopt the safety and soundness standards of the Federal banking regulatory agencies. As mentioned above, and as discussed below, although these standards are already very similar, there are a few changes to our rule. Finally, while we retain two of our existing requirements regarding the characteristics of residential property, the final rule eliminates the rest of these requirements as unnecessary and burdensome.[100]

The final rule defines a residential mortgage exposure as an exposure (other than a securitization exposure or equity exposure) that is primarily secured by a first or subsequent lien on one-to-four family residential property, provided that the dwelling (including attached components such as garages, porches, and decks) represents at least 50 percent of the total appraised value of the collateral secured by the first or subsequent lien.[101]

The final rule assigns a residential mortgage exposure to the 50-percent risk-weight category if the property is either owner-occupied or rented[102] and if the exposure was made in accordance with prudent underwriting standards suitable for residential property, including standards relating to the loan amount as a percentage of the appraised value of the property;[103] is not 90 days or more past due or carried in non-accrual status; and is not restructured or modified.[104]

A System institution must assign a 100-percent risk weight to all residential mortgage exposures that do not satisfy the criteria for a 50-percent risk weight.

The final rule maintains the current risk-based capital treatment for residential mortgage exposures that are guaranteed by the U.S. Government or U.S. Government agencies. Accordingly, residential mortgage exposures that are unconditionally guaranteed by the U.S. Government or a U.S. Government agency receive a 0-percent risk weight, and residential mortgage exposures that are conditionally guaranteed by the U.S. Government or a U.S. Government agency receive a 20-percent risk weight.

Under the final rule, a residential mortgage exposure may be assigned to the 50-percent risk-weight category only if it is not restructured or modified. We believe this new restriction on System institution risk weighting, which the Federal banking regulatory agencies adopted, is appropriate based on risk.

However, a residential mortgage exposure modified or restructured on a permanent or trial basis solely pursuant to the U.S. Treasury's Home Affordable Mortgage Program (HAMP) is not considered to be restructured or modified and continues to receive a 50-percent risk weighting. Treating mortgage loans modified pursuant to HAMP in this manner is appropriate in light of the special and unique incentive features of HAMP, and the fact that the program is offered by the U.S. Government to achieve the public policy objective of promoting sustainable loan modifications for homeowners at risk of foreclosure in a way that balances the interests of borrowers, servicers, and lenders.[105]

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[97] Section 615.5211(c)(2).

[98] *See* definition of *qualified residential loan* in § 615.5201. In addition to these credit risk standards, qualified residential loans must also satisfy a number of criteria designed to ensure that the property is residential in nature. The conditions for a loan to be considered nonaccrual are set forth in § 621.6(a) of the FCA's regulations. This final rule does not change that provision.

[99] These agencies retained their existing risk-weighting requirements for residential mortgage exposures when they adopted their new capital rules.

[100] Although the final rule deletes the specific requirements in this area, FCA examiners will continue to verify that residential property securing an exposure risk weighted as a residential mortgage exposure does in fact exhibit characteristics of residential rather than agricultural property. If examiners determine that the property is agricultural in nature, they will require appropriate adjustment of the risk-based capital treatment.

[101] To ensure that the collateral is primarily residential rather than agricultural in nature, the final rule revises the definition adopted in the U.S. rule to include the requirement regarding the appraised value of the dwelling relative to the value of the collateral as a whole.

[102] The FCA's final risk-weighting provisions do not expand the lending authorities of System institutions.

[103] The requirement that the underwriting standards be suitable for residential property is the other requirement the final rule adds to ensure that the collateral is primarily residential rather than agricultural in nature.

[104] The FCA's existing regulation does not prohibit loans that have been restructured or modified from receiving a 50-percent risk weight. The other requirements of the final rule carry over from our existing regulation.

System institutions should be mindful that the residential mortgage market is likely to change in the future, in part because of regulations the CFPB is adopting to improve the quality of mortgage underwriting and to reduce the associated credit risk and in part for market-driven or other reasons. The FCA may propose changes in the treatment of residential mortgage exposures in the future. If so, we intend to take into consideration structural and product market developments, other relevant regulations, and potential issues with implementation across various product types.

8. High Volatility Commercial Real Estate Exposures

We proposed to assign a 150-percent risk weight to HVCRE exposures, unless those exposures satisfied one or more of four specified exemptions. Because the System Comment Letter identified this as one of its threshold issues, we discuss this issue above, in Section I.D.8. of this preamble. As explained in that section, we are not finalizing the provisions governing HVCRE exposures at this time, but we expect that we will engage in additional rulemaking or issue guidance on HVCRE exposures in the future.

9. Past Due and Nonaccrual Exposures

Under the FCA's existing risk-based capital rules, the risk weight of a loan does not change if the loan becomes past due or enters nonaccrual status, with the exception of certain residential mortgage loans. Like the Federal banking regulatory agencies, however, the FCA believes that a higher risk weight is appropriate for past due and nonaccrual exposures (such as past due or nonaccrual agricultural or other borrower loans) to reflect the increased risk associated with such exposures. We adopt without modification the proposed treatment of past due and nonaccrual exposures, which reflects the impaired credit quality of such exposures.

The final rule requires a System institution to assign a risk weight of 150 percent to an exposure that is not guaranteed or is not secured by financial collateral (and that is not a sovereign exposure or a residential mortgage exposure) if it is 90 days or more past due or recognized as nonaccrual.[106] We believe this risk weight is appropriate and that any increased capital burden, potential rise in procyclicality, or impact on lending associated with the increased risk weight is justified given the overall objective of capturing the risk associated with the impaired credit quality of these exposures.

Moreover, the increased risk weight does not double-count the risk of a past due or nonaccrual exposure, even though the ALL is already reflected in the risk-based capital numerator, because the ALL is intended to cover estimated, incurred losses as of the balance sheet date, not unexpected losses. The higher risk weight on past due and nonaccrual exposures ensures sufficient regulatory capital for the increased probability of unexpected losses on these exposures.

Rather than assigning a 150-percent risk weight under this section, a System institution is permitted to assign a risk weight pursuant to §§ 628.36 and 628.37 to the portion of a past due or nonaccrual exposure that is collateralized by financial collateral or that is guaranteed if the financial collateral, guarantee, or credit derivative meets the requirements for recognition described in those sections.[107]

The System Comment Letter agreed that our proposed risk weight for past due exposures was consistent with that of the Federal banking regulatory agencies, but it expressed concern that the FCA, as a matter of examination practice, has been prescriptive and slow to recognize the performance of a loan that is in past due or nonaccrual status. The Letter stated that the FCA's approach has resulted in a significant level of cash-basis nonaccrual loans, and it asked the FCA to provide improved examination direction for the movement of loans from nonaccrual to accrual.

An association commented that System institutions are much more conservative than commercial banks in their willingness to move accounts into nonaccrual status even if the loans remain in compliance and are current, as evidenced by the high percentage of current nonaccrual loans. This association asserted that requiring 50-percent additional capital for these loans will create an incentive to loosen these conservative standards, and it recommended that we revise the rule to apply only to exposures that are both 90 days past due and nonaccrual (rather than either 90 days past due or nonaccrual, as in the proposed rule). Alternatively, the association requested that we delete the nonaccrual standard completely and retain only the 90 days past due standard.

We decline to change, in this rulemaking, either our existing regulations governing nonaccrual status or the regulation governing risk weights for past due and nonaccrual loans that we now adopt. FCA's standards for nonaccrual loans are generally similar, although not identical, to those of the Federal banking regulatory agencies.[108] Although there may be some differences in standards that would result in some loans being considered nonaccrual in the System but not nonaccrual by a commercial bank, we believe nonaccrual exposures have more risk and therefore that a higher risk weight is warranted.[109]

Nevertheless, we appreciate the comments we received on this issue. The FCA's Spring 2016 Regulatory Projects Plan, adopted by the FCA Board on February 11, 2016, indicates that we are reviewing, through April 2016, a project that would consider amendments to the criteria for reinstating nonaccrual loans under § 621.9.[110]

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[105] The U.S. rule establishes risk weights for "pre-sold residential construction loans" and "statutory multifamily mortgages." These are loans that are authorized by statutes that do not apply to System institutions, and therefore we do not adopt risk weights for them.

[106] FCA regulations at subpart C of part 621 govern loan performance and valuation assessment. A loan is considered nonaccrual if it meets any of the conditions specified in § 621.6(a). A loan may be reinstated to accrual status if it meets each of the criteria specified in § 621.9.

[107] Final § 628.2 defines financial collateral as collateral in the form of, in pertinent part, cash, investment grade debt instruments that are not resecuritization exposures, publicly traded equity securities and convertible bonds, and mutual fund (including money market fund) shares if a price is publicly quoted daily, in which the System institution has a perfected, first-priority security interest (except for cash). Financial collateral does not include collateral such as real estate (whether agricultural or not) or chattel.

[108] The Federal banking regulatory agencies do not appear to define nonaccrual standards by regulation. In its Instructions for Preparation of Consolidated Reports of Condition and Income (call report instructions), however, the Federal Financial Institutions Examination Council (FFIEC) defines nonaccrual status and explains when an asset is to be reported as being in nonaccrual status. The FFIEC is a formal interagency body established by law in 1979 and empowered, among other things, to prescribe uniform principles, standards, and report forms for the Federal examination of financial institutions by the Federal banking regulatory agencies. The instructions for FFIEC 031 (filed by banks with foreign offices) and FFIEC 041 (filed by banks without foreign offices) define "nonaccrual status" in the glossary (pp. A–59—A–62) and explain when an asset is to be reported as being in nonaccrual status (pp. RC–N–2—RC–N–3). These call report instructions were last updated in June 2015.

[109] As discussed above, our existing capital rules assign a 50 percent risk weight to "qualified residential loans," the definition of which includes that such loans are not 90 days or more past due or carried in nonaccrual status, while all other residential loans are assigned a 100 percent risk weight.

[110] *http://www.fca.gov/Download/RegProjPlanSpring2016.pdf.*

10. Other Assets

Generally consistent with our existing risk-based capital rules, the final rule assigns the risk weights described below for the following exposures:

(1) A 0-percent risk weight to cash owned and held in all offices of the System institution, in transit, or in accounts at a depository institution or a Federal Reserve Bank; to gold bullion held in a depository institution's vaults on an allocated basis to the extent gold bullion assets are offset by gold bullion liabilities; and to exposures that arise from the settlement of cash transactions (such as equities, fixed income, spot foreign exchange and spot commodities) with a central counterparty where there is no assumption of ongoing counterparty credit risk by the central counterparty after settlement of the trade;

(2) A 20-percent risk weight to cash items in the process of collection;

(3) A 100-percent risk weight to DTAs arising from temporary differences relating to net operating loss carrybacks;

(4) A 100-percent risk weight to all MSAs; and

(5) A 100-percent risk weight to all assets not specifically assigned a different risk weight under this rule (other than exposures that would be deducted from tier 1 or tier 2 capital pursuant to § 628.22).

As discussed above, the FCA's final rule, unlike the U.S. rule, requires a System institution to deduct from capital all DTAs, other than those arising from temporary differences that relating to net operating loss carrybacks. In addition, because System institutions have such little exposure to MSAs, the final rule simplifies the capital treatment that would apply under the U.S. rule. Accordingly, we risk weight DTAs and MSAs as stated above rather than adopting the capital treatment, including the 250-percent risk weight, adopted in the U.S. rule.[111]

11. Exposures to Other System Institutions

Under final § 628.22, as discussed above, a System institution must deduct from regulatory capital all equity investments (including preferred stock) in another System institution, and therefore we do not provide a risk weighting for these investments. These investments could include, for example, an association's investment in a System bank and a System bank's investment in an association.

System institutions have the authority to enter into loss-sharing agreements with other System institutions under § 614.4340. If System institutions enter into a loss-sharing agreement in the future, the FCA would assign a risk weight for any associated exposures at that time, using our regulatory reservation of authority.

12. Specialized Exposures

By FCA Bookletter BL–052, dated January 25, 2006, the FCA permitted loans recorded before January 1, 2006 that were supported by Tobacco Buyout assignments to be risk weighted at 20 percent.[112] FCA Bookletter BL–052 will remain in effect for the duration of these loans. Accordingly, this capital treatment does not need to be addressed in this final rule, and no additional guidance is necessary.

By FCA Bookletter BL–053, dated February 27, 2007, the FCA permitted System institutions to assign a lower risk weight than would otherwise apply to certain electrical cooperative assets, based on the unique characteristics and lower risk profile of this industry segment.[113] We did not propose this favorable risk weighting for these exposures in this rule, but we sought comment as to whether we should retain this risk weighting. Because the System Comment Letter identified this as one of its threshold issues, we discuss this issue above, in Section I.D.7. of this preamble. As explained in that section, we do not include this lower risk weight for exposures to electric cooperative assets in this final rule, but FCA Bookletter BL–053 remains in effect. We continue to evaluate the comments we have received and anticipate that we will issue further guidance on the capital treatment of these exposures in the future.

C. Off-Balance Sheet Items

1. Credit Conversion Factors (CCF)

Under this final rule, as under our existing risk-based capital rules, a System institution calculates the exposure amount of an off-balance sheet item by multiplying the off-balance sheet component, which is usually the contractual amount, by the applicable CCF. This treatment applies to off-balance sheet items, such as commitments, contingent items, guarantees, certain repo-style transactions, financial standby letters of credit, and forward agreements.

We proposed to impose the risk weight and CCF requirements on the unused commitment of a System bank to an association to fund the direct loan.[114] The agreement by a System bank to fund an association's direct loan satisfies the rule's definition of commitment, which is "any legally binding agreement that obligates a System institution to extend credit or to purchase assets."[115] Moreover, as discussed in the preamble to the proposed rule, we believe these commitments carry risk that warrants the holding of capital against them.

Because the System Comment Letter identified this as one of its threshold issues, we discuss this issue above, in Section I.D.9. of this preamble. We discuss several technical and mechanical issues in this section.

This final rule clarifies that unused commitments on bank loans to OFIs are also subject to this capital treatment. Although it was not stated explicitly in the proposed rule, it was clear from the definition of "commitment" that commitments from banks to OFIs were included in this provision.[116]

We provide the clarification that several commenters sought on the mechanics of the capital calculation. One commenter asked FCA to confirm that a 20-percent CCF would be applied to the wholesale unused commitment and that a 20-percent risk weight would be applied to the association obligor. With respect to associations, we confirm both of these interpretations. Under final § 628.33(b)(2)(iii), a System bank's unused commitment to an association that is not unconditionally cancelable by the System bank is assigned a 20-percent CCF, regardless of maturity. And final § 628.32(c) assigns a 20-percent risk weight to an exposure to a GSE (other than an equity exposure or preferred stock), including direct loans from System banks to associations.[117]

Another commenter presumed, since the GFA is usually a multi-year agreement, that a 50-percent CCF would be assigned to the commitment. As discussed above, the final rule assigns a

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[111] If a System institution were to increase significantly its exposures to MSAs, we would consider exercising our authority to require a higher risk weight.

[112] Such loans recorded after this date were required to be risk weighted at 100 percent.

[113] We authorized this treatment under our regulatory reservation of authority.

[114] Such a commitment is not unconditionally cancelable by the System bank. Under the GFA that governs the commitment, a System bank must continue to fund the direct loan as long as the association or OFI satisfies specified conditions.

[115] Section 628.2.

[116] We note that FCA regulation § 614.4560 requires System banks and OFIs to execute GFAs that are subject to the same regulations that bank-association GFAs are subject to.

[117] The unused commitment of a bank to an OFI that is not unconditionally cancelable by the System bank is also subject to a 20-percent CCF, regardless of maturity. As discussed above, OFI exposures are assigned a risk weight of 20 percent, 50 percent, or 100 percent, depending on the OFI.

20-percent CCF to the commitment, regardless of its term, whether it is to an association or to an OFI.

A commenter asked how the commitment amount should be calculated, since the excess amount of the borrowing base changes on a daily basis. As discussed above, FCA regulation § 614.4125(d), which requires the GFA or promissory note to establish a maximum credit limit determined by objective standards, requires the maximum credit limit to be a specific dollar amount rather than an amount based on the daily borrowing base. Final § 628.33(a)(5) provides that the exposure amount of a System bank's unused commitment to an association or OFI is the difference between the association's or OFI's maximum credit limit with the System bank (as established by the general financing agreement or promissory note, as required by § 614.4125(d)) and the amount the association or OFI has borrowed from the System bank. For example, if a System bank has a $100 maximum credit limit to an association or OFI and the association or OFI has $80 outstanding on its direct loan, the System bank's exposure amount on its unused commitment would be $20.

A commenter asked how frequently this calculation should be performed. An institution must remain above the minimum capital requirements at all times, and it must therefore perform the calculation as often as is necessary to ensure compliance with these regulations.

Similar to the current risk-based capital rules, under the final rule a System institution would apply a 0-percent CCF to the unused portion of commitments that are unconditionally cancelable by the institution. Unconditionally cancelable means a commitment that a System institution may, at any time, with or without cause, refuse to extend credit under the commitment (to the extent permitted under applicable law). In the case of an operating line of credit, a System institution is deemed able to unconditionally cancel the commitment if it can, at its option, prohibit additional extensions of credit, reduce the credit line, and terminate the commitment to the full extent permitted by applicable law. If a System institution provides a commitment that is structured as a syndication, it is required to calculate the exposure amount only for its pro rata share of the commitment.

The final rule maintains the current 20-percent CCF for self-liquidating, trade-related contingencies with an original maturity of 14 months or less.[118] In addition, the final rule increases the CCF from 0 percent to 20 percent for commitments with an original maturity of 14 months or less that are not unconditionally cancelable by a System institution.

As under our existing risk-based capital rules, under the final rule a System institution would apply a 50-percent CCF to unused commitments with an original maturity of more than 14 months that are not unconditionally cancelable by the institution (except, as discussed above, commitments of System banks to fund direct loans to associations or OFIs, which have a CCF of 20 percent) and to transaction-related contingent items, including performance bonds, bid bonds, warranties, and performance standby letters of credit.

Under this final rule, a System institution would be required to apply a 100-percent CCF to off-balance sheet guarantees, repurchase agreements, credit-enhancing representations and warranties that are not securitization exposures, securities lending and borrowing transactions, financial standby letters of credit, forward agreements, and other similar exposures. The off-balance sheet component of a repurchase agreement equals the sum of the current fair values of all positions the System institution has sold subject to repurchase. The off-balance sheet component of a securities lending transaction is the sum of the current fair values of all positions the System institution has lent under the transaction. For securities borrowing transactions, the off-balance sheet component is the sum of the current fair values of all non-cash positions the institution has posted as collateral under the transaction. In certain circumstances, a System institution may instead determine the exposure amount of the transaction as described in § 628.37 of the final rule.

In contrast to our existing risk-based capital rules, which require capital for securities lending and borrowing transactions and repurchase agreements only if they generate an on-balance sheet exposure, the final rule requires a System institution to hold risk-based capital against all repo-style transactions (that is, repurchase agreements, reverse repurchase agreements, securities lending transactions, and securities borrowing transactions), regardless of whether they generate on-balance sheet exposures, as described in § 628.37 of the final rule. For example, capital is required against the cash receivable that a System institution generates when it borrows a security and posts cash collateral to obtain the security. We adopt this approach because System institutions face counterparty credit risk when engaging in repo-style transactions, even if those transactions do not generate on-balance sheet exposures, and thus these transactions should not be exempt from risk-based capital requirements.

2. Credit-Enhancing Representations and Warranties

Consistent with our existing risk-based capital rules, under the final rule a System institution is subject to a risk-based capital requirement when it provides credit-enhancing representations and warranties on assets sold or otherwise transferred to third parties, as such positions are considered recourse arrangements.[119]

A System institution is required to hold capital only for the maximum contractual amount of its exposure under the representations and warranties, not against the value of the underlying loan. Moreover, a System institution must hold capital for the life of a credit-enhancing representation and warranty, but not after its expiration, regardless of the maturity of the underlying loan.

D. Over-the-Counter Derivative Contracts

We proposed capital treatment that would require a System institution to hold risk-based capital for counterparty credit risk for an OTC derivative contract. We received no comments on this proposed capital treatment, and we adopt it as proposed.

As defined in final § 628.2, a derivative contract is a financial contract whose value is derived from the values of one or more underlying assets, reference rates, or indices of asset values or reference rates. A derivative contract includes interest rate, exchange rate, equity, commodity, credit, and any other derivative contract that poses similar counterparty credit risks. Derivative contracts also include unsettled securities, commodities, and foreign exchange transactions with a contractual settlement or delivery lag that is longer than the lesser of the market standard for the particular instrument or 5 business days. This applies, for example, to mortgage-backed securities (MBS) transactions that the GSEs conduct in the To-Be-Announced market.

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[118] As under our existing rules, we adopt a 14-month rather than a 12-month original maturity because the agricultural production cycle and related marketing efforts typically extend beyond 12 months. A 14-month maturity allows a commitment for an operating loan to cover an entire cycle. A new commitment would be issued for the next cycle. Allowing more favorable capital treatment for a 14-month rather than a 12-month commitment does not materially raise risk in the portfolios of System institutions.

[119] Sections 615.5201 and 615.5210.

Under the final rule, an OTC derivative contract does not include a derivative contract that is a cleared transaction, which is subject to a specific treatment as described elsewhere in this preamble.

The preamble to the proposed rule explains how to determine the risk weighted asset amount for a single OTC derivative contract that is not subject to a qualifying master netting agreement and for multiple OTC derivative contracts subject to a qualifying master netting agreement.[120] It also explains how to recognize, in risk weighting OTC derivative contracts, the risk mitigation benefits of financial collateral and credit derivatives.[121]

Rather than repeating the discussion of this capital treatment that we provided in the preamble to the proposed rule, we invite interested persons to review the discussion in that preamble.[122]

E. Cleared Transactions

Like the BCBS and the Federal banking regulatory agencies, the FCA supports incentives designed to encourage clearing of derivative and repo-style transactions[123] through a central counterparty (CCP) wherever possible in order to promote transparency, multilateral netting, and robust risk management practices. Although there are some risks associated with CCPs, we believe that CCPs generally help improve the safety and soundness of the derivatives and repo-style transactions markets through the multilateral netting of exposures, establishment, and enforcement of collateral requirements, and the promotion of market transparency.

We adopt without change the capital treatment that we proposed for cleared transactions. We received one comment that supported this proposed capital treatment.[124]

Under the final rule, a System institution, acting as a clearing member client, is required to hold risk-based capital for all of its cleared transactions. The preamble to the proposed rule explains the definition of cleared transaction, as well as other relevant terms, such as clearing member client. It also explains that derivative transactions must satisfy additional criteria to be cleared transactions and that derivative transactions that do not meet these additional criteria are OTC derivative transactions. In addition, it explains the capital treatment for cleared transactions.

Rather than repeating the discussion of this capital treatment that we provided in the preamble to the proposed rule, we invite interested persons to review the discussion in that preamble.[125]

F. Credit Risk Mitigation

System institutions use a number of techniques to mitigate credit risks. For example, a System institution may collateralize exposures with cash or securities; a third party may guarantee an exposure; a System institution may buy a credit derivative to offset an exposure's credit risk; or a System institution may net exposures with a counterparty under a netting agreement.

The final rule adopts without change the proposed rule's approach to allowing System institutions to recognize the risk-mitigation effects of guarantees, credit derivatives, and collateral for risk-based capital purposes. We received one comment that supported this proposed capital treatment.[126]

As the preamble to the proposed rule explains, a System institution generally may use a substitution approach to recognize the credit risk mitigation effect of an eligible guarantee from an eligible guarantor and the simple approach to recognize the credit risk mitigation effect of collateral. That preamble explains these approaches in detail.

The preamble to the proposed rule also explains that although the use of credit risk mitigants may reduce or transfer credit risk, it simultaneously may increase other risks, including operational, liquidity, or market risk. Accordingly, a System institution is expected to employ robust procedures and processes to control risks, including roll-off and concentration risks, and monitor and manage the implications of using credit risk mitigants for the institution's overall credit risk profile.

Rather than repeating the discussion of this capital treatment that we provided in the preamble to the proposed rule, we invite interested persons to review the discussion in that preamble.[127]

G. Unsettled Transactions

The final rule provides for a separate risk-based capital requirement for transactions involving securities, foreign exchange instruments, and commodities that have a risk of delayed settlement or delivery. This capital requirement does not, however, apply to certain types of transactions, including:

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[120] The Federal banking regulatory agencies and the Federal Housing Finance Administration, together with the FCA, have adopted a rule that establishes minimum margin requirements for covered swap entities. 80 FR 74040, November 30, 2015. That margin rule permits a covered swap entity to calculate variation margin requirements on an aggregate, net basis under an eligible master netting agreement with a counterparty. In order to minimize operational burden for a covered swap entity, which otherwise would have to make a separate determination as to whether its netting agreements meet the requirements of this capital rule as well as comply with the margin rule, the definition of eligible master netting agreement in the margin rule aligns with the definition of qualifying master netting agreement in this capital rule. Like the proposed capital rule, however, this final capital rule uses the term "qualifying master netting agreement" to avoid confusion with and distinguish from the term used under the margin rules.

[121] Final § 628.2 defines financial collateral as collateral in the form of, in pertinent part, cash, investment grade debt instruments that are not resecuritization exposures, publicly traded equity securities and convertible bonds, and mutual fund (including money market fund) shares if a price is publicly quoted daily, in which the System institution has a perfected, first-priority security interest (except for cash). Financial collateral does not include collateral such as real estate (whether agricultural or not) or chattel.

[122] *See* Section IV.D. of the preamble to the proposed rule, 79 FR 52838–52840, September 4, 2014.

[123] *See* § 628.2 of the final rule for the definition of a repo-style transaction.

[124] The Federal banking regulatory agencies adopted regulatory provisions contemplating that their regulated banking organizations could act as clearing members as well as clearing member clients. We did not propose comparable provisions based on our belief that System institutions would not want to act as clearing members because of the complexity, and we stated that in the absence of such regulations, we could address risk-weighting issues on a case-by-case basis. In response to our specific invitation for comment on whether we should adopt such provisions, the System Comment Letter agreed with our omission, stating that the commenters applauded FCA's overall philosophical approach of not including complicated provisions that are not currently applicable and, as a result, are unnecessary. Accordingly, the final rule, like the proposed rule, contains no such provisions.

[125] *See* Section IV.E. of the preamble to the proposed rule, 79 FR 52840–52842, September 4, 2014.

[126] Unlike the Federal banking regulatory agencies, we did not propose to permit System institutions to calculate market price volatility and foreign exchange volatility using their own internal estimates. We explained that we believed, due to the complexity of developing and using these estimates, that no System institution would be likely to use its own estimates of haircuts, and we noted that even without such a provision, we would be able to permit a System institution to use its own estimates in the future on a case-by-case basis, using standards similar to those contained in the U.S. rule.

In response to our request for comment on whether our regulation should permit the use of a System institution's own estimates, the System Comment Letter stated that it saw no need for a provision of this nature. It stated that the provisions we had proposed appear currently workable for the System, and it applauded the FCA for not including provisions that are not currently applicable or expected to be needed any time soon. Accordingly, like the proposed rule, the final rule does not permit System institutions to calculate market price volatility and foreign exchange volatility using their own internal estimates.

[127] *See* Section IV.F. of the preamble to the proposed rule, 79 FR 52842–52846, September 4, 2014.

(1) Cleared transactions that are marked-to-market daily and subject to daily receipt and payment of variation margin;

(2) Repo-style transactions, including unsettled repo-style transactions;

(3) One-way cash payments on OTC derivative contracts; or

(4) Transactions with a contractual settlement period that is longer than the normal settlement period (which the rule defines as the lesser of the market standard for the particular instrument or 5 business days).[128]

Under the final rule, in the case of a system-wide failure of a settlement, clearing system, or central counterparty, the FCA may waive risk-based capital requirements for unsettled and failed transactions until the situation is rectified.

This capital treatment is unchanged from that in the proposal. We received no comments on this proposed capital treatment.

The preamble to the proposed rule explains that the rule provides separate treatments for delivery-versus-payment (DvP) and payment-versus-payment (PvP) transactions with a normal settlement period, and non DvP/PvP transactions with a normal settlement period. It explains these transactions and their capital treatments.

Rather than repeating the discussion of this capital treatment that we provided in the preamble to the proposed rule, we invite interested persons to review the discussion in that preamble.[129]

H. Risk Weighted Assets for Securitization Exposures

Under the FCA's existing risk-based capital rules, a System institution may use external ratings issued by NRSROs to assign risk weights to certain recourse obligations, residual interests, direct credit substitutes, asset-backed securities (ABS), and MBS. The final rule revises the risk-based capital framework for securitization exposures. These revisions include removing references to and reliance on credit ratings to determine risk weights for these exposures and using alternative standards of creditworthiness, as required by section 939A of the Dodd-Frank Act. In addition, we update the terminology for the securitization framework, include a definition of a securitization exposure that encompasses a wider range of exposures with similar risk characteristics, and implement new due diligence requirements for securitization exposures.

The final rule adopts without change the proposed risk-based capital framework for securitization exposures. The final rule defines a securitization exposure as an on- or off-balance sheet credit exposure (including credit-enhancing representations and warranties) that arises from a traditional or synthetic securitization (including a resecuritization), or an exposure that directly or indirectly references a securitization exposure.

The preamble to the proposed rule (1) explains that the securitization framework is designed to address the credit risk of exposures that involve the tranching of the credit risk of one or more underlying financial exposures;[130] (2) provides an overview of the securitization framework and explains the definitions of terms used in the framework, such as traditional securitization, synthetic securitization, and resecuritization exposure; (3) explains the operational requirements for institutions using the securitization framework, including due diligence requirements; (4) explains that System institutions generally must calculate a risk weighted asset amount for a securitization exposure by applying either the simplified supervisory formula approach or a gross-up approach; (5) explains how to determine the exposure amount of a securitization exposure; and (6) explains exceptions under the securitization framework, alternative treatments for certain types of securitization exposures, and other important matters.

Rather than repeating the comprehensive discussion of this capital treatment that we provided in the preamble to the proposed rule, we invite interested persons to review the discussion in that preamble.[131] We received two comments on this proposed capital treatment, which we now address.

First, we received comments on the omission of references to asset-backed commercial paper (ABCP) programs in the proposed rule. The U.S. rule excludes certain exposures to asset-backed commercial paper (ABCP) programs from the definition of resecuritization exposure. That rule defines an ABCP program as a program established primarily for the purpose of issuing commercial paper that is investment grade and backed by underlying exposures held in a bankruptcy-remote special purpose entity.

The System has access to the capital markets through the Funding Corporation; we believe it unlikely that a System institution would establish an ABCP program, because if the Funding Corporation's ability to issue debt ever was impeded, we believe the ability of an ABCP program to issue commercial paper would face the same difficulties. Accordingly, in the interest of simplifying our regulations where possible, we proposed to make no reference to ABCP programs.

In response to our specific request for comment as to whether we should include provisions in our risk-based capital rules regarding ABCP programs that are comparable to those in the U.S. rule, the System Comment Letter stated that our reason for proposing to omit ABCP provisions seemed reasonable and logical, that it seemed unlikely that either the System or an individual System bank would seek to establish an ABCP program, and that in the unlikely event they did want to establish such a program, the FCA could address it on a case-by-case basis. The Letter concluded, therefore, that ABCP provisions are unnecessary. Accordingly, the final rule, like the proposed rule, makes no reference to ABCP programs.

Second, we received comments on the due diligence requirements that we proposed for securitization exposures. Like the U.S. rule, our proposed due diligence requirements were designed to address the concern among regulators that during the recent financial crisis, many banking organizations relied exclusively on NRSRO ratings and did not perform their own credit analysis of the securitization exposures.

Our proposed rule would have required a System institution to demonstrate, to the FCA's satisfaction, a comprehensive understanding of the features of a securitization exposure that would materially affect the exposure's performance. The proposed rule would have required the System institution's analysis to be commensurate with the complexity of the exposure and the materiality of the exposure in relation to capital of the institution. On an on-going basis (no less frequently than quarterly), the System institution would have been required to evaluate, review, and update as appropriate the analysis required under § 628.41(c)(1) for each securitization exposure. The pre- and periodic post-acquisition analysis of the exposure's risk characteristics would have had to consider:

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[128] Such transactions are treated as derivative contracts as provided in § 628.34 or § 628.35 of the rule.

[129] *See* Section IV.G. of the preamble to the proposed rule, 79 FR 52846–52847, September 4, 2014.

[130] Only those MBS that involve tranching of credit risk are considered securitization exposures. Mortgage-backed pass-through securities (for example, those guaranteed by Freddie Mac or Fannie Mae) that feature various maturities but do not involve tranching of credit risk do not meet the definition of a securitization exposure. These securities are risk weighted in accordance with the general risk-weighting provisions.

[131] *See* Section IV.H. of the preamble to the proposed rule, 79 FR 52847–52854, September 4, 2014.

(1) Structural features of the securitization that would materially affect the performance of the exposure, for example, the contractual cash flow waterfall, waterfall-related triggers, credit enhancements, liquidity enhancements, fair value triggers, the performance of organizations that service the position, and deal-specific definitions of default;

(2) Relevant information regarding the performance of the underlying credit exposure(s), for example, the percentage of loans 30, 60, and 90 days past due; default rates; prepayment rates; loans in foreclosure; property types; occupancy; average credit score or other measures of creditworthiness; average LTV ratio; and industry and geographic diversification data on the underlying exposure(s);

(3) Relevant market data on the securitization, for example, bid-ask spread, most recent sales price and historical price volatility, trading volume, implied market rating, and size, depth and concentration level of the market for the securitization; and

(4) For resecuritization exposures, performance information on the underlying securitization exposures, for example, the issuer name and credit quality, and the characteristics and performance of the exposures underlying the securitization exposures.

Under the proposed rule, if the System institution was not able to meet these due diligence requirements and demonstrate a comprehensive understanding of a securitization exposure to the FCA's satisfaction, the institution would have been required to assign a risk weight of 1,250 percent to the exposure.

The System Comment Letter asserted that these due diligence requirements for "investment securities" contained in proposed § 628.41(c) significantly overlapped with the existing regulatory requirements on investment management in subpart E of part 615. The result, according to the Letter, would be significant redundancy and regulatory burden. The commenters asked us to make conforming changes to either the proposed capital rules or the existing investment management rules to eliminate duplication and potentially conflicting requirements.

We note, contrary to the assertion of the System Comment Letter, that the new due diligence requirements contained in proposed § 628.41(c) do not apply to "investment securities". Rather, this regulation applies to securitization exposures, the definition of which is discussed above. In contrast, our investment management regulations in subpart E of part 615, including the due diligence requirements at § 615.5133(f), apply only to investments that System banks and associations are authorized to hold for specified purposes. These investments must satisfy FCA's eligibility requirements or be specifically approved by FCA.[132]

If a System institution has a securitization exposure that is subject to our investment management regulations, then both our investment management due diligence regulation and the new securitization exposure due diligence regulation would apply. If, however, a System institution has a securitization exposure that is not subject to our investment management regulations, then only the securitization exposure due diligence regulation would apply, and not our investment management due diligence regulation. And if a System institution has an investment subject to our investment management regulations that is not a securitization exposure, then only our investment management due diligence regulation would apply, and not the new securitization exposure due diligence regulation.

Accordingly, for some exposures, only one due diligence regulation applies. Securitization exposures that are subject to our investment management regulations, however, are subject to both due diligence regulations. We do not believe these two due diligence regulations conflict with each other. Some requirements are contained in one regulation but not the other. For example, our investment management regulations require stress testing, while the securitization exposure regulation does not. Securitization exposures that are subject to our investment management regulations, therefore, like other investments, are subject to the investment management stress testing requirements.

Some requirements, such as risk analysis or value determination, are set forth in both regulations. For securitization exposures that are subject to our investment management regulations, institutions must fulfill the requirements of both regulations, but if one analysis or determination satisfies both regulations, they only need to perform it once, thus eliminating any potential duplication.

Because any potential overlaps can be satisfied with a single analysis or determination, we do not believe it is burdensome for an institution to have to comply with both regulations. Accordingly, we decline to change either of these regulations.

I. Equity Exposures

As discussed above, under § 628.22, a System institution must deduct from regulatory capital all equity investments (including preferred stock) in another System institution. Section 628.22 also requires a System institution to deduct from regulatory capital all equity investments in a service corporation or the Funding Corporation. Accordingly, we do not assign a risk weighting for these equity investments.

This final rule revises our existing risk-based capital rules' treatment for equity exposures that are not to other System institutions, service corporations, or the Funding Corporation. Institutions could acquire such exposures, for example, by making equity investments in UBEs,[133] by making equity investments in rural business investment companies (RBICs),[134] by making equity investments that the FCA approves under § 615.5140(e), and by acquiring equity exposures pledged as collateral in a loan or derivative transaction.

The rule requires a System institution to apply the Simple Risk-Weight Approach for equity exposures that are not exposures to an investment fund and to apply certain look-through approaches to assign risk weighted asset amounts to equity exposures to an investment fund.

We received no comments on the capital treatment for equity exposures that we proposed. We adopt this capital treatment without change, except for the following. We do not adopt the provisions we proposed assigning risk weights to equity exposures authorized under FCA regulation § 615.5140(e). System institutions are authorized to acquire equity exposures under that regulation only with FCA's prior approval, and we assign a risk weight as a condition of that approval. Accordingly, it is unnecessary to assign a risk weight to such exposures by regulation.

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[132] *See* §§ 615.5132, 615.5140, and 615.5142.

[133] System institutions have the authority to invest in UBEs under FCA regulations at subpart J of part 611.

[134] Authority for System institutions to invest in RBICs is governed by 7 U.S.C. 2009cc *et seq.*; these investments do not require the FCA's approval. However, a System institution that wishes to invest in a UBE organized for investing in an RBIC must comply with FCA's UBE regulations at subpart J of part 611.

The preamble to the proposed rule explains the definition of equity exposure and exposure measurement. It explains how to calculate the risk weight for various equity exposures, including those that form effective hedge pairs. It also explains the three methods of assigning risk weights to equity exposures to investment funds. Rather than repeating the discussion of this capital treatment that we provided in the preamble to the proposed rule, we invite interested persons to review the discussion in that preamble.[135]

V. Market Discipline and Disclosure Requirements

Meaningful public disclosure by banking organizations is one of the three pillars of the Basel framework. Public disclosure complements the minimum capital requirements and the supervisory review process by encouraging market discipline. The other Federal banking regulatory agencies adopted disclosure requirements for the banking organizations that they regulate with $50 billion or more in assets.

We proposed similar disclosure requirements for System banks on a bank-only basis (not on a consolidated, district-wide basis). In our proposal, we explained that the disclosure requirements are appropriate for all System banks—even those that currently have less than $50 billion in assets—because they are jointly and severally liable for the Systemwide debt obligations that they issue.[136] We further explained that a System bank's exposure to risks and the techniques that it uses to identify, measure, monitor, and control those risks are important factors that market participants consider in their assessment of the bank. We made clear that a System bank would not have to make any disclosures that do not apply to it.[137]

The proposal required each System bank to make these disclosures in its quarterly and annual reports to shareholders that are required in part 620 of our regulations.[138] We specifically addressed potential concerns about duplicative disclosures by stating that System banks would not be required to make the disclosures in the exact format set out in the proposed regulations, or in the same location in the report, as long as they provide a summary table specifically indicating the location(s) of all disclosures.

We believed the proposal struck the proper balance between the market benefits of disclosure and the burden of providing the disclosures, and we invited comment on the appropriate application of the proposed disclosure requirements to System banks.

We received comments in the System Comment Letter and from several individual System institutions on the proposed disclosure requirements. The commenters objected to these requirements because the disclosures would not be harmonized across the System; associations would have one set of disclosures, banks would have another, combined district disclosures would be different from those of the bank, and the System-wide disclosure would be different yet again. They stated that this disclosure regime is not a good fit for the federated cooperative structure of the System. They asked the FCA to work with System banks on appropriate enhancements to the existing required disclosures in part 620 through other guidance, such as an Informational Memorandum, stating that this approach would be more flexible and not encumber the regulations with excessive requirements that apply to only four entities.

These comments do not persuade us to change the disclosure requirements we proposed. As discussed above, our existing regulations in part 620 require each System institution to prepare annual and quarterly reports. The regulations we proposed and that we now adopt without substantive change require System banks to disclose additional information that is particularly relevant to market participants as they assess the System's risk, providing a more transparent picture of System institutions' capital to the investment-banking sector.

We understand that any change in disclosure requirements may increase burden, as parties are required to disclose information they have never previously had to disclose. We believe, however, that the benefit of these additional disclosures outweighs any burden that might result. The disclosure requirements are similar to those adopted by the Federal banking regulatory agencies. As discussed above and in the preamble to our proposed rule, the System urged the FCA to adopt a capital framework that was as similar as possible to the U.S. rule, asserting that consistency and transparency would allow investors, shareholders, and others to better understand the financial strength and risk-bearing capacity of the System. We believe this rule accomplishes that objective.

A System bank also commented that the requirement is unfair because the four System banks are independent institutions with separate boards of directors, different charters, and diverse business models, and the total assets of two of the banks are below the $50 billion threshold that would trigger the requirement under the U.S. rule. Even though the banks are directed and managed independently of each other, we believe that all four of them—even those that currently have less than $50 billion in assets—should be required to make these disclosures. Each bank is jointly and severally liable for the System-wide debt obligations that they issue; market participants would be unable to assess the risk in the debt without having access to this information from all four banks.

Accordingly, we adopt as final our proposal to require all System banks to make disclosures, without substantive change other than to reflect differences from the proposed capital requirements. Rather than repeating the discussion of these disclosure requirements that we provided in the preamble to the proposed rule, we invite interested persons to review the discussion that preamble.[139]

VI. Conforming and Clarifying Changes

The proposed rule contained a number of conforming changes to current FCA regulations. Except for a modification of the proposed change to § 614.4351 as discussed below, we adopted the proposed changes in the final rule. We also added numerous additional nonsubstantive clarifying and conforming changes that were not in the proposed rule, primarily adding references in existing rules to the new part 628. The changes include:

In § 607.2(b), which defines "average risk-adjusted asset base" for purposes of the FCA's assessment and apportionment of administrative expenses, we replaced the reference to § 615.5210 with a reference to § 615.5201.

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[135] *See* Section IV.I. of the preamble to the proposed rule, 79 FR 52854–52857, September 4, 2014.

[136] Nothing in this proposed regulation or preamble would change any of our existing regulatory requirements, including those in part 620 or part 621.

[137] For example, Table 1 requires a System bank to make certain disclosures about subsidiaries. If a System bank has no subsidiaries, it does not have to make those disclosures.

[138] Sections 620.2 and 620.4 of the FCA's regulations require each System institution to prepare, provide to the FCA and shareholders, and make available to the public an annual report after the end of each fiscal year. Sections 620.2 and 620.10 require each System institution to prepare, provide to the FCA and shareholders, and make available to the public a quarterly report after the end of each fiscal quarter (except the fiscal quarter that coincides with the end of the System institution's fiscal year).

[139] *See* Section V. of the preamble to the proposed rule, 79 FR 52857–52859, September 4, 2014.

In § 611.1265(e), which pertains to an institution in the process of terminating Farm Credit status, we deleted a reference to subpart K of part 615 and added a reference to part 628.

In proposed § 614.4351(a)(3), which describes the lending and leasing limit base for System institutions, we proposed to replace the reference to total surplus with a reference to tier 2 capital. The System Comment Letter pointed out that our proposed change had the potential effect of excluding third-party preferred stock from an institution's lending and leasing limit base if such stock is excluded under new § 628.23 from the institution's tier 1 and tier 2 capital. We agree with the System that our proposed change could have had this unintended effect. In the final rule, we have modified the language to ensure the inclusion of excess third-party capital under § 628.23 in the lending and leasing limit base, provided such preferred stock is otherwise includible in tier 1 or tier 2 capital.

In § 615.5143(a) and (b), pertaining to the management of ineligible investments, we removed references to net collateral.

In § 615.5200, which contains capital planning requirements, we removed references to total capital, surplus, core surplus, total surplus, and unallocated surplus; we added references to CET1, tier 1 capital, total capital, and tier 1 leverage ratio and made other minor nonsubstantive and technical changes. We also made a number of substantive changes in § 615.5200 that are described above in Section D.3. of this preamble.

In § 615.5201, we removed of definitions that are no longer used in revised part 615, subpart H, including "bank," "commitment," "credit conversion factor," "credit derivative," "credit-enhancing interest-only strip," "credit-enhancing representations and warranties," "deferred-tax assets that are dependent on future income or future events," "direct credit substitute," "direct lender institution," "externally rated," "face amount," "financial asset," "financial standby letter of credit," "Government agency," "Government-sponsored agency," "institution," "nationally recognized statistical rating organization," "non-OECD bank," "OECD," "OECD bank," "performance-based standby letter of credit," "qualified residential loan," "qualifying bilateral netting contract," "qualifying securities firm," "recourse," "residual interest," "risk participation," "Rural Business Investment Company," "securitization," "servicer cash advance," "total capital," "traded position," and "U.S. depository institution"; we revised the definitions of "permanent capital" and "risk-adjusted asset base"; and we added definitions of "deferred tax assets," "System bank," and "System institution." We also added back the definition of "allocated investment," which was inadvertently transferred to part 628 definitions in the proposed rule.

In §§ 615.5206 and 615.5208, we removed references to the defunct Farm Credit System Financial Assistance Corporation (FAC) in § 615.5206(a); we removed §§ 615.5206(d) and 615.5208(c), which pertain to the FAC; and we made other minor nonsubstantive and technical changes.

In § 615.5207, which pertains to adjustments in the permanent capital computation, we made revisions in paragraph (f) to require deduction of an investment in the Funding Corporation and in paragraph (j) to eliminate the exclusion of AOCI and to require the exclusion of any defined benefit pension fund net asset, in order to make the deductions from the numerator of the permanent capital calculation consistent with the deductions from the denominator.

We removed §§ 615.5209 through 615.5212, which pertain to risk-weighting for the permanent capital ratio. Under the final rule, the denominator of the permanent capital ratio will be computed using the risk weightings in part 628.

In § 615.5220, which pertains to the capitalization bylaws, we made minor nonsubstantive and technical changes.

In § 615.5240, which sets forth a number of permanent capital requirements, we added a reference to the regulatory capital standards in proposed part 628.

In § 615.5250, which contains disclosure requirements for borrower stock, we added references to the regulatory capital standards in part 628.

In § 615.5255, which contains disclosure and review requirements for other equities, we added a reference to the new part 628 capital standards as suggested by the System Comment Letter and made minor nonsubstantive and technical changes. We did not make other changes requested by the System. In the event a disclosure statement is deemed to be cleared 60 days after receipt by the FCA of a proposed disclosure statement under paragraph (f), we did not add a reference to new part 628 that would have permitted the institution to treat the proposed issuance as CET1, additional tier 1, or tier 2 capital. This is consistent with the existing regulation's approach to core surplus, total surplus, and net collateral. We also did not shorten the FCA review period from 30 days to 5 days in paragraph (h) or the review period from 60 days to 30 days in paragraph (f). The suggested timeframes are not adequate for the agency's review procedures. In the case of third-party capital issuances, we are sensitive to the fact that institutions often have tight timeframes related to market expectations and timing, and we believe that we have been able to accommodate requests to expedite our review procedures whenever feasible.

We revised § 615.5270, pertaining to the retirement of equities other than eligible (protected) borrower stock, to incorporate restrictions and limits on redemptions of equities that are included in tier 1 and tier 2 capital.

In § 615.5290, pertaining to the retirement of capital stock and participation certificates in the event of restructuring, we made minor nonsubstantive and technical changes.

In § 615.5295, which pertains to the payment of dividends, we added a reference to part 628.

We removed part 615, subpart K, which contained the requirements for the core surplus, total surplus, and net collateral standards.

In §§ 615.5350, 615.5352, and 615.5355, pertaining to the establishment of minimum capital ratios for an individual institution, we replaced references to core surplus, total surplus, and net collateral with references to tier 1 and tier 2 capital.

In § 620.5, which lists the required contents of a System institution's annual report, we replaced references to core surplus, total surplus, and net collateral with references to the new part 628 regulatory capital requirements (including initial compliance plans under § 628.301) in paragraphs (d)(1)(ix), (f)(2) and (3), and (g)(4). In addition, we added a new paragraph (4) in § 620.5(f) to require disclosure of the core surplus, total surplus, and net collateral ratios in System institutions' annual reports for the years 2017–2021 for as long as these years are part of the "previous 5 fiscal years" for which disclosures are required.

We revised § 620.17, pertaining to notifying stockholders when a System institution falls below minimum capital requirements, to expand the notification requirement to include the regulatory capital standards in part 628.

In § 624.12, pertaining to the margin and capital requirements for covered swap entities, we added a reference to part 628 in paragraph (b).

In § 627.2710, which sets forth the grounds for appointing a conservator or receiver, we deleted references to the total surplus and net collateral ratios.

VII. Timeframe for Implementation

Our proposed rule provided for an effective date of January 1, 2016. In the final rule, we are adopting an effective date of January 1, 2017.

We also proposed a 3-year phase-in period for the capital conservation buffer but without any transition or phase-in periods for regulatory adjustments to or deductions in the regulatory capital calculations. By contrast, Basel III and the U.S. rule have, in addition to the capital conservation buffer, numerous phase-in and transition periods for the capital regulations lasting from 2014 (2015 for banking organizations not using the advanced approaches rules) until 2019 or after. Many of the transition provisions pertain to regulatory deductions and adjustments, minority interests, and temporary inclusion of non-qualifying instruments. We have determined that most of the transition and phase-in periods are not needed to give System institutions sufficient time to come into compliance with the new standards.

We have analyzed every System institution's call report data for September 30, 2015. In our analysis, we first assumed that all institutions would extend their redemption and revolvement programs to 7 years and would adopt required bylaw provisions or an annual board resolution for inclusion in CET1 capital. Under this scenario, we concluded that all System institutions would meet all the minimum amounts including the buffers for the final CET1, tier 1 and total capital risk-based ratios if those requirements were in effect today. We then assumed, alternatively, that those institutions that redeem allocated equities would not extend their revolvement periods to 7 years and could not include them under CET1. Under this scenario as well, these institutions would still exceed the minimum capital requirements. Therefore, based on current information, all System institutions should exceed the minimum regulatory ratios on the effective date of the rule. The FCA believes that most, if not all, System institutions would adopt a bylaw provision or annual board resolution to ensure that the non-qualified allocated equities they do not redeem will meet the definition of URE equivalents, and that those equities that are routinely redeemed will be included in CET1.

For the risk weightings, we used current risk weights under FCA's existing capital regulations. For System associations, we assumed the final risk weightings would not be materially different from existing risk weightings in existing regulations. The most significant change to risk weights for associations would be past-due and non-accrual exposures, as well as the credit conversation factors for certain unused commitments. As just stated, we believe the changes in risk weights for associations would result in a negligible impact to current risk weighted asset amounts and that it is appropriate to use existing risk weights in our analysis.

For System banks, we believe that certain new risk weights or conversion factors could have a material impact. For instance, System banks will need to hold additional capital for their unconditionally cancelable unused commitments, as well as the unused commitments on the direct loans to their affiliated associations. To account for the new risk weights, our analysis increased risk-adjusted assets by 20 percent for each bank. With this increase, all banks still exceeded the minimum amounts (including the buffers) for the final CET1, tier 1 and total capital risk-based ratios. Our existing core surplus rules require both banks and associations to exclude shared capital; however, under the Tier 1/Tier 2 Capital Framework, System banks will be able to count the stock and equities they have issued or allocated to System associations in their regulatory capital ratios.

All System institutions would meet the 4.0 percent minimum tier 1 leverage ratio and 1 percent leverage buffer (including the 1.5-percent component of the ratio for URE and equivalents) if the final requirements were effective today. Our analysis indicates that the leverage ratio would not be a constraining ratio for System associations because total assets closely parallel risk-adjusted assets and the associations have strong tier 1 capital levels. The leverage ratios for associations will be similar to their tier 1 capital risk-based ratios. If the final rule were effective today, all System banks would exceed the 4.0 percent minimum tier 1 leverage ratio and 1-percent leverage buffer; however, one bank, which had a 5.4-percent tier 1 leverage ratio on September 30, 3015, would be near the leverage buffer requirement. Additionally, all System banks would significantly exceed the 1.5-percent URE and URE equivalents component of the minimum leverage ratio. This analysis assumed that System banks would be able to include all their non-qualified allocated surplus as URE equivalents. The System banks' tier 1 leverage ratios would be significantly lower than their tier 1 risk-based ratios because a large portion of their loans are to their affiliated associations and are risk weighted at 20 percent.

The final rule includes a phase-in period for the capital conservation buffer beginning January 1, 2017, with the buffer fully phased-in beginning January 1, 2020. Unlike the U.S. rule's adjustments and deductions transitions, the calculation of our capital conservation buffer will not change over the phase-in period, and there will be no additional burden on System institutions to revise how it is calculated each year. Rather, the amount of the minimum capital conservation buffer increases every year until fully phased-in. The transition period for the U.S. rule began in 2015 and will be fully phased in as of January 1, 2019. As noted above, the FCA's final rule will become effective for the reporting periods beginning in 2017.

In the event that some System institutions do not meet the tier 1 and tier 2 minimum capital ratios as of the effective date, the final rule permits them to comply by submitting a capital restoration plan. The plan requires FCA approval, and the institution will be required to submit its proposed plan within 20 days of the quarter-end during which the new capital standards become effective—*i.e.,* March 31, 2017. The plan must describe how the institution proposes to achieve and maintain compliance with the new requirements, demonstrating progress towards meeting that goal. If the FCA does not approve the plan, the institution must revise and re-submit the plan. There is a list of factors in the final rule that the FCA will consider in evaluating a plan. They include: (1) Circumstances leading to the institution's decrease in capital and whether they were caused by the institution or by circumstances beyond the institution's control; (2) the institution's financial ratios (*e.g.,* capital, adverse assets, ALL) compared to those of its peers or industry norms; (3) the institution's previous compliance practices; and (4) the views of the institution's directors and managers regarding the plan. If the capital restoration plan is adopted by the institution and approved by the FCA within 180 days of the quarter-end in which the tier 1 and tier 2 capital requirements become effective, the institution will be deemed to be in compliance with the requirements.[140]

VIII. Abbreviations

ABCP—Asset-Backed Commercial Paper
ABS—Asset-backed Security
ADC—Acquisition, Development, or Construction
AFS—Available For Sale
ALL—Allowance for Loan Losses
AOCI—Accumulated Other Comprehensive Income
BCBS—Basel Committee on Banking Supervision
BHC—Bank Holding Company
CCF—Credit Conversion Factor
CCP—Central Counterparty
CDS—Credit Default Swap
CEIO—Credit-Enhancing Interest-Only Strip
CEM—Current Exposure Method
CFR—Code of Federal Regulations
CFPB—Consumer Financial Protection Bureau
CFTC—Commodity Futures Trading Commission
CPSS—Committee on Payment and Settlement Systems
CRC—Country Risk Classifications
CUSIP—Committee on Uniform Securities Identification Procedures
DAC—Deferred Acquisition Cost
DCO—Derivatives Clearing Organizations
DTA—Deferred Tax Asset
DTL—Deferred Tax Liability
DvP—Delivery-versus-Payment
E—Measure of Effectiveness
EE—Expected Exposure
ERISA—Employee Retirement Income Security Act of 1974
FCA—Farm Credit Administration
FDIC—Federal Deposit Insurance Corporation
FDICIA—Federal Deposit Insurance Corporation Improvement Act of 1991
FFIEC—Federal Financial Institutions Examination Council
FHA—Federal Housing Authority
FHLB—Federal Home Loan Bank
FHLMC—Federal Home Loan Mortgage Corporation
FIRREA—Financial Institutions, Reform, Recovery and Enforcement Act
FMU—Financial Market Utility
FNMA—Federal National Mortgage Association
FR—Federal Register
GAAP—Generally Accepted Accounting Principles (U.S.)
GNMA—Government National Mortgage Association
GSE—Government-Sponsored Enterprise
HAMP—Home Affordable Mortgage Program
HOLA—Home Owners' Loan Act
HTM—Held to Maturity
HVCRE—High-Volatility Commercial Real Estate
IFRS—International Financial Reporting Standards
IOSCO—International Organization of Securities Commissions
LTV—Loan-to-Value Ratio
MBS—Mortgage-backed Security
MDB—Multilateral Development Bank
MHC—Mutual Holding Company
MSA—Mortgage Servicing Assets
NRSRO—Nationally Recognized Statistical Rating Organization
OCC—Office of the Comptroller of the Currency
OECD—Organization for Economic Cooperation and Development
OFI—Other Financing Institution
OMB—Office of Management and Budget
OTC—Over-the-Counter
OTTI—Other Than Temporary Impairment
PFE—Potential Future Exposure
PMI—Private Mortgage Insurance
PMSR—Purchased Mortgage Servicing Right
PSE—Public Sector Entities
PvP—Payment-versus-Payment
QCCP—Qualifying Central Counterparty
QIS—Quantitative Impact Study
QM—Qualified Mortgage
RBA—Ratings-Based Approach
RBC—Risk-Based Capital
REIT—Real Estate Investment Trust
Re-REMIC—Resecuritization of Real Estate Mortgage Investment Conduit
SAP—Statutory Accounting Principles
SEC—Securities and Exchange Commission
SFA—Supervisory Formula Approach
SLHC—Savings and Loan Holding Company
SPE—Special Purpose Entity
SRWA—Simple Risk-Weight Approach
SSFA—Simplified Supervisory Formula Approach
U.S.C.—United States Code
VA—Department of Veterans Affairs
VOBA—Value of Business Acquired
WAM—Weighted Average Maturity

IX. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the FCA hereby certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Each of the banks in the Farm Credit System, considered together with its affiliated associations, has assets and annual income in excess of the amounts that would qualify them as small entities. Therefore, Farm Credit System institutions are not "small entities" as defined in the Regulatory Flexibility Act.[141]

Addendum: Discussion of the Final Rule

Overview

The FCA is adopting this final rule (final rule or rule) to update the regulatory capital rules for the System to include provisions consistent with those suggested by the Basel Committee on Banking Supervision (BCBS) to the international regulatory capital framework, the U.S. rule, and the requirements of the Dodd-Frank Act. Among other things, the final rule:

- Establishes a minimum risk-based common equity tier 1 (CET1) risk-based ratio of 4.5 percent;
- Establishes a minimum tier 1 risk-based ratio of 6 percent;
- Establishes a minimum total capital risk-based ratio of 8 percent;
- Establishes a minimum tier 1 leverage ratio of 4 percent, of which at least 1.5 percent must consist of unallocated retained earnings (URE) and URE equivalents;
- Establishes a capital conservation buffer of 2.5 percent and a leverage buffer of 1 percent below which an institution's discretionary capital distributions and bonuses would be limited or prohibited without FCA approval;
- Increases capital requirements for past-due and nonaccrual loans and certain short-term unused loan commitments;
- Expands the recognition of collateral and guarantors in determining risk weighted assets;
- Removes references to credit ratings;
- Establishes due diligence requirements for securitization exposures; and
- Increases required regulatory capital disclosures of System banks.

This addendum summarizes the final rule. The FCA intends for this addendum to act as a guide for System institutions to navigate the rule and identify the provisions that may be most relevant to them, but it is not comprehensive. The FCA expects and encourages all System institutions to review the final rule in its entirety.

We remind System institutions that the presence of a particular risk weighting does not itself provide authority for a System institution to have an exposure to that asset or item.

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[140] This final rule is modeled after current § 615.5336, which was adopted in 1997 at the time the FCA adopted the core surplus, total surplus and net collateral requirements. Several System institutions achieved initial compliance with those requirements.

[141] The System Comment Letter questioned our RFA certification. In the proposed rule, we certified that the rule would not have a significant economic impact on a large number of small entities. Our certification considered each System bank together with "its affiliated associations." The System objected to our combining associations with System banks, stating that because each institution has to comply with the regulatory requirements each should be considered individually for purposes of identifying economic impact.

As we stated in the preamble to the final merger rule published August 24, 2015 (80 FR 51113), the RFA definition of a small entity incorporates the Small Business Administration (SBA) definition of a "small business concern," including its size standards. A small business concern is one independently owned and operated, and not dominant in its field of operation. For purposes of the RFA, the interrelated ownership, supervisory control, and contractual relationship between associations and their funding banks are the basis for FCA's conclusion to treat them as a single entity. Therefore, System institutions do not satisfy the RFA definition of "small entities." *See* 80 FR 51113 (August 24, 2015).

A. Capital Components

1. Common Equity Tier 1 Capital (CET1)

(a) Common cooperative equities (purchased member stock, purchased participation certificates, and allocated equities) with the following key criteria (among others):

- Borrower stock (regardless of redemption or revolvement period) up to the statutory minimum of $1000 or 2 percent of the loan amount, whichever is less;
- Equities are perpetual;
- Equities subject to discretionary revolvement or redemption are not retired for at least 7 years after issuance;
- Equities can be retired only with FCA prior approval (unless it is the statutory minimum borrower stock requirement or unless the distribution meets "safe harbor" standards) and the System institution has a capitalization bylaw or board of directors resolution (which must be re-affirmed annually) providing that it must obtain FCA approval prior to redeeming or revolving any equities it includes in CET1 before the end of the 7-year period;
- Equities represent a claim subordinated to all preferred stock, all subordinated debt, and all liabilities of the institution in a receivership, liquidation, or similar proceeding;

(b) Unallocated retained earnings (URE); and

(c) Paid-in capital resulting from a merger of System institutions or repurchase of third-party capital.

In the final rule, System institutions are not required to include accumulated other comprehensive income in CET1.

2. Additional Tier 1 Capital (AT1)

Equities other than common cooperative equities (*i.e.,* equities issued primarily to third-party investors) that meet most of the CET1 criteria, except that AT1 capital equities represent a claim that ranks senior to all common cooperative equities in a receivership, liquidation, or similar proceeding.

3. Tier 2 Capital

(a) Equities, which may be common cooperative equities or equities held by third parties, not includable in Tier 1 with the following key criteria:

- Equities are perpetual or have an original maturity of at least 5 years;
- Equities subject to discretionary revolvement or redemption are not retired for at least 5 years after issuance; and
- Equities may not be redeemed or revolved prior to maturity or the end of the stated revolvement period without FCA prior approval (unless the distribution meets "safe harbor" standards);

(b) Subordinated debt that is not callable for at least 5 years and not subject to acceleration except in the event of a receivership, liquidation, or similar proceeding; and

(c) Allowance for losses (ALL) up to 1.25 percent of total risk weighted assets.

4. Regulatory Adjustments and Deductions

(a) Deductions From CET1 Capital

- Goodwill, intangible assets, gains-on-sale in connection with a securitization exposure, defined benefit pension fund net assets, and deferred tax assets due to net operating loss carryforwards, all of which are net of associated deferred tax liabilities; and
- The System institution's allocated equity investments in another System institution.

(b) Deductions From Regulatory Capital Using the Corresponding Deduction Approach

A System institution's purchased equity investments in other System institutions must be deducted using the corresponding deduction approach. This means that a System institution would make deductions from the component of capital for which the underlying instrument qualified if it were issued by the System institution itself.

5. FCA Prior Approval of Cash Patronage Refunds, Cash Dividend Payments, and Allocated Equity Redemptions; "Safe Harbor" Treatment for Certain Such Payments

FCA prior approval would be required for redemption of equities included in tier 1 and tier 2, comparable to Basel III and the banking agencies' rule. Prior approval is also required for cash dividends and cash patronage payments in excess of a specified level, comparable to U.S. banking law and regulations. Exceptions to the FCA prior approval requirement are that System institutions can redeem member stock up to an amount equal to the Farm Credit Act's minimum member-borrower stock requirement of $1,000 or 2 percent of the member's loan, whichever is less. In addition, this amount of borrower stock would not have to be outstanding for a minimum period of 7 years in order for the institution to include it in CET1. However, redemptions of such amounts of stock would be included in the calculation for the "safe harbor" in proposed § 628.22(f)(5).

Under the proposed "safe harbor," FCA prior approval is deemed to be granted (*i.e.,* a request for approval does not have to be made to the FCA) for cash distributions to pay dividend, patronage payments, or redemptions or revolvements of common cooperative equities provided that:

(a) For revolvements or redemptions of common cooperative equities included in CET1 capital, such equities were issued or allocated at least 7 years before the revolvement or redemption (except the equities are not subject to the 7-year minimum if they are held by the estate of a deceased former borrower, if the institution is required to redeem or revolve the equities under a § 615.5290 restructuring, or if a court order requires the institution to redeem or revolve the equities);

(b) For redemptions or revolvements of common cooperative equities included in Tier 2 capital, such equities were issued or allocated at least 5 years before the redemption or revolvement (except the equities are not subject to the 5-year minimum if they are held by the estate of a deceased former borrower, if the institution is required to redeem or revolve the equities under a § 615.5290 restructuring, or if a court order requires the institution to redeem or revolve the equities);

(c) After such cash payments, the dollar amount of the System institution's CET1 capital equals or exceeds the dollar amount of CET1 capital on the same date of the previous calendar year; and

(d) After such cash payments, the System institution continues to comply with all minimum regulatory capital requirements and supervisory or enforcement actions.

6. Capital Buffer Amounts

The capital conservation buffer of 2.5 percent and the leverage buffer of 1 percent provide a cushion above regulatory capital minimums. The buffers' purpose is to restrict an institution's discretionary capital distributions of earnings before that institution reaches the minimum capital requirements.

If a System institution's CET1, tier 1 *and* total capital risk-based ratios exceed minimum requirements, the capital conservation buffer is the lowest of the following:

- The System institution's CET1 capital ratio minus the System institution's minimum CET1 capital ratio of 4.5 percent;
- The System institution's tier 1 capital ratio minus the System institution's minimum tier 1 capital ratio of 6 percent; and

- The System institution's total capital ratio minus the System institution's minimum total capital ratio of 8 percent.

If the CET1 ratio, tier 1 ratio, *or* total capital ratio does not exceed minimum requirements, then the capital conservation buffer is zero.

A System institution's leverage buffer is the institution's tier 1 leverage ratio minus the minimum tier 1 leverage ratio of 4 percent. If the tier 1 leverage ratio is below 4 percent, the leverage buffer is zero.

B. Risk Weightings

1. Zero-Percent (0%) Risk Weighted Exposures

- An exposure to the U.S. Government, its central bank, or a U.S. Government agency—§ 628.32(a)(1)(i)(A);
- The portion of an exposure that is directly and unconditionally guaranteed by the U.S. Government, its central bank, or a U.S. Government agency—§ 628.32(a)(1)(i)(B);
- An exposure to a sovereign entity that meets certain criteria (as discussed below)—§ 628.32(a) and Table 1;
- Exposures to certain supranational entities and multilateral development banks—§ 628.32(b);
- Cash—§ 628.32(l);
- Certain gold bullion—§ 628.32(l);
- Certain exposures that arise from the settlement of cash transactions with a central counterparty—§ 628.32(l);
- An exposure to an OTC derivative contract that meets certain criteria—§ 628.37(b)(3)(i);
- The collateralized portion of an exposure with respect to which the financial collateral meets certain criteria—§ 628.37(b)(3)(iii); and
- An equity exposure to any entity whose credit exposures receive a 0-percent risk weight—§ 628.52(b)(1).

2. Twenty-Percent (20%) Risk Weighted Exposures

- The portion of an exposure that is conditionally guaranteed by the U.S. Government, its central bank, or a U.S. Government agency—§ 628.32(a)(1)(ii);
- An exposure to a sovereign entity that meets certain criteria (as discussed below)—§ 628.32(a) and Table 1;
- An exposure to a GSE, other than an equity exposure or preferred stock—§ 628.32(c)(1);
- Most exposures to U.S.- or state-organized depository institutions or credit unions, including those that are OFIs—§ 628.32(d)(1);
- An exposure to a foreign bank that meets certain criteria (as discussed below)—§ 628.32(d)(2) and Table 2;
- A general obligation exposure to a U.S. or state PSE—§ 628.32(e)(1)(i);
- An exposure to a non-U.S. PSE that meets certain criteria (as discussed below)—§ 628.32(e)(2), (e)(3), and (e)(4)(i) and Table 3;
- Cash items in the process of collection—§ 628.32(l)(2);
- A loan that a System bank makes to an association (a direct loan)—§ 628.32(m); and
- An equity exposure to a PSE or the Federal Agricultural Mortgage Corporation (Farmer Mac)—§ 628.52(b)(2).

3. Fifty-Percent (50%) Risk Weighted Exposures

- An exposure to a sovereign entity that meets certain criteria (as discussed below)—§ 628.32(a) and Table 1;
- An exposure to a foreign bank that meets certain criteria (as discussed below)—§ 628.32(d)(2) and Table 2;
- A revenue obligation exposure to a U.S. or state PSE—§ 628.32(e)(1)(ii);
- An exposure to a non-U.S. PSE that meets certain criteria (as discussed below)—§ 628.32(e)(2), (e)(3), (e)(4)(ii) and Tables 3 and 4;
- An exposure to an OFI that is not a depository institution or credit union but that is investment grade or that meets capital, risk identification and control, and operational standards similar to depository institutions and credit unions; and
- First lien residential mortgage exposures that meet certain criteria—§ 628.32(g).

4. One Hundred-Percent (100%) Risk Weighted Exposures

- An exposure to a sovereign entity that meets certain criteria (as discussed below)—§ 628.32(a) and Table 1;
- Preferred stock issued by a non-System GSE—§ 628.32(c)(2);
- An exposure to a foreign bank that meets certain criteria (as discussed below)—§ 628.32(d)(2) and Table 2;
- An exposure to a non-U.S. PSE that meets certain criteria (as discussed below)—§ 628.32(e)(2), (e)(3), (e)(5) and Tables 3 and 4;
- All corporate exposures—§ 628.32(f). This category would include the following:
  - ○ Borrower loans such as agricultural loans and consumer loans, regardless of the corporate form of the borrower, unless those loans qualify for different risk weights under other risk-weighting provisions;
  - ○ System bank exposures to OFIs that do not satisfy the criteria for a 20-percent or a 50-percent risk weight; and
  - ○ Premises, fixed assets, and other real estate owned;
- All residential mortgage exposures that do not satisfy the criteria for a 50-percent risk weight—§ 628.32(g);
- Deferred tax assets arising from temporary differences that could be realized through net operating loss carrybacks—§ 628.32(l)(3);
- All mortgage servicing assets—§ 628.32(l)(4);
- All assets that are not specifically assigned a different risk weight and that are not deducted from tier 1 or tier 2 capital pursuant to § 628.22—§ 628.32(l)(5);
- The effective portion of a hedge pair—§ 628.52(b)(3)(ii); and
- Non-significant equity exposures—§ 628.52(b)(3)(iii).

5. One Hundred Fifty-Percent (150%) Risk Weighted Exposures

- An exposure to a sovereign entity that meet certain criteria (as discussed below)—§ 628.32(a) and Table 1;
- A sovereign exposure, if an event of sovereign default has occurred during the previous 5 years—§ 628.32(a)(6) and Table 1;
- An exposure to a foreign bank, if an event of sovereign default has occurred during the previous 5 years in the foreign bank's home country—§ 628.32(d)(2)(iv) and Table 2;
- An exposure to a non-U.S. PSE that meets certain criteria (as discussed below)—§ 628.32(e)(2), (e)(3), (e)(5) and Tables 3 and 4;
- An exposure to a PSE, if an event of sovereign default has occurred during the previous 5 years in the PSE's home country—§ 628.32(e)(6) and Tables 3 and 4; and
- The portion of a past due or nonaccrual exposure that is not guaranteed or that is not secured by financial collateral (except for a sovereign exposure or a residential mortgage exposure, both risk weighted as discussed above)—§ 628.32(k).

6. Six Hundred-Percent (600%) Risk Weighted Exposures

- An equity exposure to an investment firm, provided that the investment firm meets specified conditions—§ 628.52(b).

7. One Thousand Two Hundred Fifty-Percent (1,250%) Risk Weighted Exposures

- Certain high-risk securitization exposures, such as CEIO strips—§§ 628.41–628.45.

8. Past Due Exposures (90 Days or More Past Due or in Nonaccrual Status)

- One hundred percent (100%)—residential mortgage exposures—§ 628.32(g);

- A System institution may assign a risk weight to the guaranteed portion of a past due or nonaccrual exposure based on the risk weight that applies under § 628.36 if the guarantee or credit derivative meets the requirements of that section—§ 628.32(k)(2);
- A System institution may assign a risk weight to the portion of a past due or nonaccrual exposure that is collateralized by financial collateral based on the risk weight that applies under § 628.37 if the financial collateral meets the requirements of that section—§ 628.32(k)(3); and
- One hundred fifty percent (150%)—all other past due and nonaccrual exposures—§ 628.32(k)

9. Conversion Factors for Off-Balance Sheet Items—§ 628.33

- Zero percent (0%)—commitment that is unconditionally cancellable by the System institution;
- Twenty percent (20%)—
  - ○ Commitment, other than a System bank's commitment to an association or OFI, with an original maturity of 14 months or less that is not unconditionally cancellable by the System institution;
  - ○ Self-liquidating, trade-related contingent items that arise from the movement of goods, with an original maturity of 14 months or less; and
  - ○ A System bank's commitment to an association or OFI that is not unconditionally cancelable by the System bank, regardless of maturity.
- Fifty percent (50%)—
  - ○ Commitments, other than a System bank's commitment to an association or OFI, with an original maturity of more than 14 months that are not unconditionally cancellable by the System institution; and
  - ○ Transaction-related contingent items, including performance bonds, bid bonds, warranties, and performance standby letters of credit;
- One hundred percent (100%)—
  - ○ Guarantees;
  - ○ Repurchase agreements (the off-balance sheet component of which equals the sum of the current fair values of all positions the System institution has sold subject to repurchase);
  - ○ Credit-enhancing representations and warranties that are not securitization exposures;
  - ○ Off-balance sheet securities lending transactions (the off-balance sheet component of which equals the sum of the current fair values of all positions the System institution has lent under the transaction);
  - ○ Off-balance sheet securities borrowing transactions (the off-balance sheet component of which equals the sum of the current fair values of all non-cash positions the System institution has posted as collateral under the transaction);
  - ○ Financial standby letters of credit; and
  - ○ Forward agreements.

10. Over-the-Counter (OTC) Derivative Contracts—§ 628.34

A System institution determines the risk-based capital requirement for a derivative contract by determining the exposure amount and then assigning a risk weight based on the counterparty or collateral. The exposure amount is the sum of current exposure plus potential future credit exposure (PFE). The current credit exposure is the greater of 0 or the mark-to-fair value of the derivative contract. The PFE is generally the notional amount of the derivative contract multiplied by a credit conversion factor for the type of derivative contract. Table 1 to § 628.34 shows the credit conversion factors for derivative contracts.

11. Treatment of Cleared Transactions—§ 628.35

The rule introduces a specific capital treatment for exposures to central counterparties (CCPs), including certain transactions conducted through clearing members by System institutions that are not themselves clearing members of a CCP. Section 628.35 describes the capital treatment of cleared transactions and of default fund exposures to CCPs, including more favorable capital treatment for cleared transactions through CCPs that meet certain criteria.

12. Treatment of Guarantees—§ 628.36

The rule allows a System institution to substitute the risk weight of an eligible guarantor for the risk weight otherwise applicable to the guaranteed exposure. This treatment applies only to *eligible guarantees* and *eligible credit derivatives,* and it provides certain adjustments for maturity mismatches, currency mismatches, and situations where restructuring is not treated as a credit event. To be an *eligible guarantee,* the guarantee must be from an *eligible guarantor* (as defined in the rule) and must satisfy the definitional requirements of *eligible guarantee.*

13. Treatment of Collateralized Transactions—§ 628.37

The rule allows System institutions to recognize the risk-mitigating benefits of financial collateral (as defined) in risk weighted assets. In all cases, the System institution must have a perfected, first priority interest in the financial collateral.

Where the collateral satisfies specified criteria, a System institution may use the simple approach—that is, it may apply a risk weight to the portion of an exposure that is secured by the fair value of financial collateral by using the risk weight of the collateral. There is a general risk weight floor of 20 percent.

For repo-style transactions, eligible margin loans, collateralized derivative contracts, and single-product netting sets of such transactions, a System institution may instead use the collateral haircut approach—that is, it may reduce the amount of exposure to be risk weighted (rather than substituting the risk weight of the collateral).

A System institution must use the same approach for similar exposures or transactions.

14. Unsettled Transactions—§ 628.38

The rule provides for a separate risk-based capital requirement for transactions involving securities, foreign exchange instruments, and commodities that have a risk of delayed settlement or delivery. This capital requirement does not, however, apply to certain types of transactions, including cleared transactions that are marked-to-market daily and subject to daily receipt and payment of variation margin. The rule contains separate treatments for delivery-versus-payment (DvP) and payment-versus-payment (PvP) transactions with a normal settlement period, and non-DvP/non-PvP transactions with a normal settlement period.

15. Securitization Exposures—§§ 628.41–628.45

The rule introduces due diligence and other requirements for System institutions that own, originate, or purchase securitization exposures and introduces a new definition of securitization exposure. Under the rule, a System institution that originates the underlying exposures included in a securitization could have a securitization exposure and, if so, would be subject to the requirements.

Note that mortgage-backed pass-through securities (for example, those guaranteed by the Federal Home Loan Mortgage Corporation or the Federal National Mortgage Association) do not meet the definition of a securitization exposure because they do not involve a tranching of credit risk. Rather, only those MBS that involve tranching of credit risk are securitization exposures.

16. Equity Exposures—§§ 628.51–628.52

A System institution must apply a simple risk-weight approach (SRWA) to determine the risk weight for equity exposures that are not exposures to an investment fund.

17. Equity Exposures to Investment Funds—§ 628.53

The approaches described in this section apply to equity exposures to investment funds such as mutual funds, but not to hedge funds or other leveraged investment funds. For exposures to investment funds, a System institution must use one of three risk-weighting approaches: The full-look through approach; the simple modified look-through approach; or the alternative modified look-through approach.

18. Foreign Exposures —§ 628.32(a), (d), and (e), and Tables 1, 2, 3, and 4

A System institution must risk weight an exposure to a foreign government, foreign public sector entity (PSE), and a foreign bank based on the Country Risk Classification (CRC) that is applicable to the foreign government, or the home country of the foreign PSE or foreign bank. If a foreign country does not have a CRC, the risk weighting for its government, PSEs, and banks depends on whether or not the country is a member of the Organization for Economic Cooperation and Development (OECD). A sovereign exposure is assigned a 150-percent risk weight immediately upon determining that an event of sovereign default has occurred, or if an event of sovereign default has occurred during the previous 5 years.

The risk weights for foreign sovereigns, foreign banks, and foreign PSEs are shown in the tables below:

TABLE 1—RISK WEIGHTS FOR FOREIGN SOVEREIGN EXPOSURES

	Risk weight (in percent)
Sovereign CRC:	
0–1	0
2	20
3	50
4–6	100
7	150
OECD Member with no CRC	0
Non-OECD Member with no CRC	100
Sovereign Default	150

TABLE 2—RISK WEIGHTS FOR EXPOSURES TO FOREIGN BANKS

	Risk weight (in percent)
Sovereign CRC:	
0–1	20
2	50
3	100
4–7	150
OECD Member with no CRC	20
Non-OECD Member with no CRC	100
Sovereign Default	150

TABLE 3—RISK WEIGHTS FOR FOREIGN PSE GENERAL OBLIGATIONS

	Risk weight (in percent)
Sovereign CRC:	
0–1	20
2	50
3	100
4–7	150
OECD Member with no CRC	20
Non-OECD Member with no CRC	100
Sovereign Default	150

TABLE 4—RISK WEIGHTS FOR FOREIGN PSE REVENUE OBLIGATIONS

	Risk weight (in percent)
Sovereign CRC:	
0–1	50
2–3	100
4–7	150
OECD Member with no CRC	50
Non-OECD Member with no CRC	100
Sovereign Default	150

19. Summary Comparison of Current Risk-Weighting Rules Versus Revised Risk-Weighting Rules

Category	Current risk weight (in general)	Revised risk weight under Final Rules	Comments
Risk Weights for On-Balance Sheet Exposures Under Current and Revised Rules			
Cash	0%	0%.	
Direct exposures to or unconditionally guaranteed by the U.S. Government, its central bank, or a U.S. Government agency.	0%	0%.	
Exposures to certain supranational entities and multilateral development banks.	20%	0%.	
Cash items in the process of collection.	20%	20%.	
Conditional exposures to the U.S. Government.	20%	20%	A conditional exposure is one that requires the satisfaction of certain conditions, for example, servicing requirements.
Exposures to Government-sponsored entities (GSEs).	20% (including preferred stock).	20%—exposures other than preferred stock and equity exposures. 100%—preferred stock of non-System GSEs All System equities, including preferred stock, deducted from capital (not risk weighted).	
Most exposures to U.S. depository institutions or credit unions (including those that are OFIs).	20%	20%.	
Exposures to U.S. public sector entities (PSEs).	20%—general obligations 50%—revenue obligations	20%—general obligations. 50%—revenue obligations.	

Category	Current risk weight (in general)	Revised risk weight under Final Rules	Comments
Exposures to other System institutions that are not deducted from tier 1 or tier 2 capital.	20%	20%.	
Corporate exposures (including exposures to agricultural borrowers and to OFIs that do not satisfy the criteria for a lower risk weight).	100%—generally 50%—lower risk OFIs that do not satisfy the criteria for 20%.	100%—generally 50%—lower risk OFIs that do not satisfy the criteria for 20%.	
Past due and nonaccrual exposures.	Generally no change when an exposure is past due or in nonaccrual status. Past due or nonaccrual residential loans—100%.	100%—residential mortgage exposures 150%—all other exposures, for the portion that is not guaranteed or secured by financial collateral.	90 days or more past due or in nonaccrual.
Servicing assets	100% (not specifically addressed)—mortgage servicing assets (MSAs) and non-MSAs.	100%—MSAs (Non-MSAs deducted from capital).	
Deferred tax assets	Certain DTAs deducted from capital. Other DTAs—100% (not specifically addressed).	100%—DTAs arising from temporary differences relating to net operating carrybacks. DTAs deducted from CET1 arise from net operating carryforwards.	
Assets not specifically assigned to a risk-weight category and not deducted from tier 1 or tier 2 capital.	100%	100%	Includes: —borrower loans such as agricultural loans and consumer loans, unless qualify for 50% risk weighting. —premises, fixed assets, and other real estate owned.
Exposures to foreign governments and their central banks.	0% for direct and unconditional claims on OECD governments. 20% for conditional claims on OECD governments. 100% for claims on non-OECD governments.	Risk weight depends on Country Risk Classification (CRC) applicable to the sovereign. If there is no CRC, depends on OECD membership. Risk weights range between 0% and 150%. 150% for a sovereign that has defaulted within the previous 5 years.	
Exposures to foreign banks	20% for claims on banks in OECD countries. 20% for short-term claims on banks in non-OECD countries. 100% for long-term claims on banks in non-OECD countries.	Risk weight depends on home country's CRC rating. If there is no CRC, depends on OECD membership of home country. Risk weights range between 20% and 150%. 150% in the case of a sovereign default in the bank's home country.	
Claims on foreign PSEs	20% for general obligations of states and political subdivisions of OECD countries. 50% for revenue obligations of states and political subdivisions of OECD countries. 100% for all obligations of states and political subdivisions of non-OECD countries.	Risk weight depends on the home country's CRC. If there is no CRC, risk depends on OECD membership of home country. Risk weights range between 20% and 150% for general obligations and between 50% and 150% for revenue obligations. 150% for a PSE in a home country with a sovereign default.	
MBS, ABS, and structured securities.	Ratings-based approach	Deduction for the after-tax gain-on-sale of a securitization. 1,250% risk weight for a CEIO 100% for interest—only MBS that are not credit-enhancing. System institutions may elect to follow a gross up approach—senior securitization tranches are assigned the risk weight associated with the underlying exposures. System institutions may instead elect to follow the simplified supervisory formula approach (SSFA)—requires various data inputs to a supervisory formula exposure. Alternatively, System institutions may apply a 1,250% risk weight to any securitization.	

Category	Current risk weight (in general)	Revised risk weight under Final Rules	Comments
Unsettled transactions	Not addressed	100%, 625%, 937.5%, and 1,250% for DvP or PvP transactions depending on the number of business days past the settlement date. 1,250% for non-DvP, non-PvP transactions more than 5 days past the settlement date. The proposed capital requirement for unsettled transactions would not apply to cleared transactions that are marked-to-market daily and subject to daily receipt and payment of variation margin.	
Equity exposures	100%	0% risk weight: equity exposures to any entity whose credit exposures receive a 0% risk weight. 20%: Equity exposures to a PSE or Farmer Mac. 100%: Equity exposures to effective portions of hedge pairs and equity exposures to non-significant equity investments. 600%: Equity exposures to investment firms that satisfy certain conditions.	
Equity exposures to investment funds.	There is a 20% risk weight floor on mutual fund holdings.	Choose among three approaches: full look-through; simple modified look-through; and alternative modified look-through. *Full look-through:* Risk weight the assets of the fund (as if owned directly) multiplied by the System institution's proportional ownership in the fund. *Simple modified look-through:* Multiply the System institution's exposure by the risk weight of the highest risk weight asset in the fund. *Alternative modified look-through:* Assign risk weight on a pro rata basis based on the investment limits in the fund's prospectus. For certain equity exposures authorized under § 615.5140(e), risk weighted asset amount = adjusted carrying value.	
		Credit Conversion Factors (CCF) Under the Current and Revised Rules	
CCF for off-balance sheet items.	0% for the unused portion of a commitment with an original maturity of 14 months or less, or which is unconditionally cancellable by the System institution at any time.	0% for the unused portion of a commitment that is unconditionally cancellable by the System institution.	
	20% for short-term, self-liquidating, trade-related contingent items.	20% for the unused portion of a commitment with an original maturity of 14 months or less that is not unconditionally cancellable by the System institution.	
	50% for the unused portion of a commitment with an original maturity of more than 14 months that is not unconditionally cancellable by the System institution.	20% for self-liquidating trade-related contingent items that arise from the movement of goods, with an original maturity of 14 months or less.	
	50% for transaction-related contingent items (performance bonds, bid bonds, warranties, and standby letters of credit).	20% for a System bank's commitment to an association or OFI that is not unconditionally cancelable by the System bank, regardless of maturity.	

Category	Current risk weight (in general)	Revised risk weight under Final Rules	Comments
	100% for guarantees, repurchase agreements, securities lending and borrowing transactions, financial standby letters of credit, and forward agreements.	50% for the unused portion of a commitment, other than a System bank's commitment to an association or OFI, over 14 months that is not unconditionally cancellable by the System institution. 50% for transaction-related contingent items (performance bonds, bid bonds, warranties, and standby letters of credit). 100% for guarantees, repurchase agreements, securities lending and borrowing transactions, financial standby letters of credit, and forward agreements.	
OTC derivative contracts (except cleared transactions).	Calculation of off-balance sheet credit equivalents based on current exposure plus potential future exposure and a set of conversion factors.	Calculation of off-balance sheet credit equivalents amount based on current exposure plus potential future exposure and a revised set of conversion factors. Recognition of credit risk mitigation of collateralized OTC derivative contracts.	
Cleared transactions	Not specifically addressed	If collateral posted with a qualified central counterparty, and subject to specific requirements, then assign 2 percent; or. If requirements not met, then assign 4 percent.	
Credit Risk Mitigation Under the Current and Revised Rules			
Guarantees	Generally recognizes guarantees provided by central governments, GSEs, PSEs in OECD countries, multilateral lending institutions, regional development institutions, U.S. depository institutions, foreign banks, and qualifying securities firms in OECD countries.	Recognizes guarantees from eligible guarantors, as defined. Substitution treatment allows the System institution to substitute the risk weight of the protection provider for the risk weight ordinarily assigned to the exposure. Applies only to eligible guarantees and eligible credit derivatives, and adjusts for maturity mismatches, currency mismatches, and where restructuring is not treated as a credit event.	Claims conditionally guaranteed by the U.S. government receive a risk weight of 20 percent.
Collateralized transactions	No recognition	For financial collateral only, the rule provides two approaches:	*Financial collateral* does not include collateral such as real estate or chattel. In all cases the System institution must have a perfected, 1st priority interest.
		1. *Simple approach* A System institution may apply a risk weight to the portion of an exposure that is secured by the fair value of collateral by using the risk weight of the collateral—with a general risk weight floor of 20%.	For the simple approach there must be a collateral agreement for at least the life of the exposure; collateral must be revalued at least every 6 months; collateral other than gold must be in the same currency.
		2. *Collateral haircut approach* A System institution may use standard supervisory haircuts for eligible margin loans, repo-style transactions, and collateralized derivative contracts.	

20. Disclosure Requirements—§§ 628.61–628.63 (Including Tables 1–10)

The rule requires each System bank, generally on a quarterly basis, to make public disclosures related to its capital requirements. Disclosures are required as follows:

Table 1—Scope of Application—Provides the basic context underlying regulatory capital calculations.

Table 2—Capital Structure—Provides summary information on the terms and conditions of the main features of regulatory capital instruments. Also requires disclosure of the total amount of CET1, tier 1, and total capital, with separate disclosures for deductions and adjustments to capital.

Table 3—Capital Adequacy—Provides information on a System bank's approach for categorizing and risk-weighting its exposures, as well as the amount of total risk weighted assets.

Table 4—Capital Buffers—Requires a System bank to disclosure the capital conservation buffer and leverage buffer, the eligible retained income and any limitations on capital distributions and certain discretionary bonus payments, as applicable.

Table 5—Credit Risk: General Disclosures—Requires a System bank to

disclose information pertaining to its general credit risk.

Table 6—General Disclosure for Counterparty Credit Risk-Related Exposures—Requires a System bank to disclose information pertaining to its counterparty credit risk.

Table 7—Credit Risk Mitigation—Requires a System bank to disclose information pertaining to credit risk mitigation.

Table 8—Securitization—Provides information to market participants on the amount of credit risk transferred and retained by a System bank through securitization transactions, the types of products involved in the System bank's securitizations, the risks inherent in the System bank's securitized assets, the System bank's policies regarding credit risk mitigation, and the names of any entities that provide external credit assessments of a securitization.[142] Securitization transactions in which the originating System bank does not retain any securitization exposure are shown separately and are reported only for the year of inception of the transaction.[143]

Table 9—Equities—Provides market participants with an understanding of the types of equity securities held by the System bank and how they are valued. Also provides information on the capital allocated to different equity products and the amount of unrealized gains and losses.

Table 10—Interest Rate Risk for Non-Trading Activities—Requires a System bank to provide certain quantitative and qualitative disclosures regarding the System bank's management of interest rate risks.

List of Subjects

12 CFR Part 607

Accounting, Agriculture, Banks, Banking, Reporting and recordkeeping requirements, Rural areas.

12 CFR Part 611

Agriculture Banks, Banking, Rural areas.

12 CFR Part 614

Agriculture, Banks, Banking, Foreign trade, Reporting and recordkeeping requirements, Rural areas.

12 CFR Part 615

Accounting, Agriculture, Banks, Banking, Government securities, Investments, Rural areas.

12 CFR Part 620

Accounting, Agriculture, Banks, Banking, Reporting and recordkeeping requirements, Rural areas.

12 CFR Part 624

Accounting, Agriculture, Banks, Banking, Capital, Cooperatives, Credit, Margin requirements, Reporting and recordkeeping requirements, Risk, Rural areas, Swaps.

12 CFR Part 627

Agriculture, Banks, Banking, Claims, Rural areas.

12 CFR Part 628

Accounting, Agriculture, Banks, Banking, Capital, Government securities, Investments, Rural areas.

For the reasons stated in the preamble, parts 607, 611, 614, 615, 620, 624, 627, and 628 of chapter VI, title 12 of the Code of Federal Regulations are amended as follows:

PART 607—ASSESSMENT AND APPORTIONMENT OF ADMINISTRATIVE EXPENSES

■ 1. The authority citation for part 607 continues to read as follows:

Authority: Secs. 5.15, 5.17 of the Farm Credit Act (12 U.S.C. 2250, 2252) and 12 U.S.C. 3025.

■ 2. Section 607.2 is amended by revising paragraph (b) introductory text to read as follows:

§ 607.2 Definitions.

* * * * *

(b) *Average risk-adjusted asset base* means the average of the risk-adjusted asset base (as defined in § 615.5201 of this chapter) of banks, associations, and designated other System entities, calculated as follows:

* * * * *

PART 611—ORGANIZATION

■ 3. The authority citation for part 611 continues to read as follows:

Authority: Secs. 1.2, 1.3, 1.4, 1.5, 1.13, 2.0, 2.1, 2.2, 2.10, 2.11, 2.12, 3.0, 3.1, 3.2, 3.21, 4.12, 4.12A, 4.15, 4.20, 4.21, 5.9, 5.17, 6.9, 6.26, 7.0–7.13, 8.5(e) of the Farm Credit Act (12 U.S.C. 2002, 2011, 2012, 2013, 2021, 2071, 2072, 2073, 2091, 2092, 2093, 2121, 2122, 2123, 2142, 2183, 2184, 2203, 2208, 2209, 2243, 2252, 2278a–9, 2278b–6, 2279a–2279f–1, 2279aa–5(e)); secs. 411 and 412 of Pub. L. 100–233, 101 Stat. 1568, 1638; sec. 414 of Pub. L. 100–399, 102 Stat. 989, 1004.

■ 4. Section 611.1265 is amended by revising paragraph (e) to read as follows:

§ 611.1265 Retirement of a terminating association's investment in its affiliated bank.

* * * * *

(e) *Exclusion of equities from capital ratios.* If another Farm Credit institution makes an agreement to retire equities you hold in that institution after termination, we may require that institution to exclude part or all of those equities from assets and capital when the institution calculates its regulatory capital under parts 615 and 628 of this chapter.

PART 614—LOAN POLICIES AND OPERATIONS

■ 5. The authority citation for part 614 continues to read as follows:

Authority: 42 U.S.C. 4012a, 4104a, 4104b, 4106, and 4128; secs. 1.3, 1.5, 1.6, 1.7, 1.9, 1.10, 1.11, 2.0, 2.2, 2.3, 2.4, 2.10, 2.12, 2.13, 2.15, 3.0, 3.1, 3.3, 3.7, 3.8, 3.10, 3.20, 3.28, 4.12, 4.12A, 4.13B, 4.14, 4.14A, 4.14C, 4.14D, 4.14E, 4.18, 4.18A, 4.19, 4.25, 4.26, 4.27, 4.28, 4.36, 4.37, 5.9, 5.10, 5.17, 7.0, 7.2, 7.6, 7.8, 7.12, 7.13, 8.0, 8.5 of the Farm Credit Act (12 U.S.C. 2011, 2013, 2014, 2015, 2017, 2018, 2019, 2071, 2073, 2074, 2075, 2091, 2093, 2094, 2097, 2121, 2122, 2124, 2128, 2129, 2131, 2141, 2149, 2183, 2184, 2201, 2202, 2202a, 2202c, 2202d, 2202e, 2206, 2206a, 2207, 2211, 2212, 2213, 2214, 2219a, 2219b, 2243, 2244, 2252, 2279a, 2279a–2, 2279b, 2279c–1, 2279f, 2279f–1, 2279aa, 2279aa–5); sec. 413 of Pub. L. 100–233, 101 Stat. 1568, 1639.

■ 6. Section 614.4351 is amended by removing paragraph (a)(2), redesignating paragraph (a)(3) as paragraph (a)(2), and revising newly redesignated paragraph (a)(2) to read as follows:

§ 614.4351 Computation of lending and leasing limit base.

(a) * * *

(2) Any amounts of preferred stock not eligible to be included in total capital as defined in § 628.2 of this chapter must be deducted from the lending limit base, except that otherwise eligible third-party capital that is required to be excluded from total capital under § 628.23 of this chapter may be included in the lending limit base.

* * * * *

PART 615—FUNDING AND FISCAL AFFAIRS, LOAN POLICIES AND OPERATIONS, AND FUNDING OPERATIONS

■ 7. The authority citation for part 615 is revised to read as follows:

Authority: Secs. 1.5, 1.7, 1.10, 1.11, 1.12, 2.2, 2.3, 2.4, 2.5, 2.12, 3.1, 3.7, 3.11, 3.25, 4.3,

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[142] For purposes of these disclosures (and these capital regulations), a System bank is considered to have securitized assets if assets that it originated or purchased from third parties are included in a securitization.

[143] A System bank is authorized to act as an "originating System institution," which the regulation defines as a System institution that directly or indirectly originated the underlying exposures included in a securitization.

4.3A, 4.9, 4.14B, 4.25, 5.9, 5.17, 6.20, 6.26, 8.0, 8.3, 8.4, 8.6, 8.7, 8.8, 8.10, 8.12 of the Farm Credit Act (12 U.S.C. 2013, 2015, 2018, 2019, 2020, 2073, 2074, 2075, 2076, 2093, 2122, 2128, 2132, 2146, 2154, 2154a, 2160, 2202b, 2211, 2243, 2252, 2278b, 2278b–6, 2279aa, 2279aa–3, 2279aa–4, 2279aa–6, 2279aa–7, 2279aa–8, 2279aa–10, 2279aa–12); sec. 301(a), Pub. L. 100–233, 101 Stat. 1568, 1608; sec. 939A, Pub. L. 111–203, 124 Stat. 1326, 1887 (15 U.S.C. 78o–7 note).

■ 8. Section 615.5143 is amended by revising paragraphs (a)(3) and (b)(4) to read as follows:

§ 615.5143 Management of ineligible investments and reservation of authority to require divestiture.

(a) * * *

(3) It must be excluded as collateral under § 615.5050.

(b) * * *

(4) You may continue to hold the investment as collateral under § 615.5050 at the lower of cost or market value; and

* * * * *

■ 9. Sections 615.5200 and 615.5201 are revised to read as follows:

§ 615.5200 Capital planning.

(a) The Board of Directors of each System institution shall determine the amount of regulatory capital needed to assure the System institution's continued financial viability and to provide for growth necessary to meet the needs of its borrowers. The minimum capital standards specified in this part and part 628 of this chapter are not meant to be adopted as the optimal capital level in the System institution's capital adequacy plan. Rather, the standards are intended to serve as minimum levels of capital that each System institution must maintain to protect against the credit and other general risks inherent in its operations.

(b) Each Board of Directors shall establish, adopt, and maintain a formal written capital adequacy plan as a part of the financial plan required by § 618.8440 of this chapter. The plan shall include the capital targets that are necessary to achieve the System institution's capital adequacy goals as well as the minimum permanent capital, common equity tier 1 (CET1) capital, tier 1 capital, total capital, and tier 1 leverage ratios (including the unallocated retained earnings (URE) and URE equivalents minimum) standards. The plan shall address any projected dividend payments, patronage payments, equity retirements, or other action that may decrease the System institution's capital or the components thereof for which minimum amounts are required by this part and part 628 of this chapter. The plan shall set forth the circumstances and minimum timeframes in which equities may be redeemed or revolved consistent with the System institution's applicable bylaws or board of directors resolutions. Such bylaws or resolutions must include the information described in paragraph (d) of this section.

(c) In addition to factors that must be considered in meeting the minimum standards, the board of directors shall also consider at least the following factors in developing the capital adequacy plan:

(1) Capability of management and the board of directors (the assessment of which may be a part of the assessments required in paragraphs (b)(2)(ii) and (b)(7)(i) of § 618.8440 of this chapter);

(2) Quality of operating policies, procedures, and internal controls;

(3) Quality and quantity of earnings;

(4) Asset quality and the adequacy of the allowance for losses to absorb potential loss within the loan and lease portfolios;

(5) Sufficiency of liquid funds;

(6) Needs of a System institution's customer base; and

(7) Any other risk-oriented activities, such as funding and interest rate risks, potential obligations under joint and several liability, contingent and off-balance-sheet liabilities or other conditions warranting additional capital.

(d) In order to include otherwise eligible purchased and allocated equities in tier 1 capital and tier 2 capital under part 628 of this chapter, a System institution must adopt a capitalization bylaw, or its board of directors must adopt a resolution, which resolution must be re-affirmed by the board on an annual basis in the capital adequacy plan, in which the institution undertakes the following:

(1) The institution shall obtain prior FCA approval under § 628.20(f) of this chapter before:

(i) Redeeming or revolving equities included in CET1 capital;

(ii) Redeeming or calling equities included in additional tier 1 capital; and

(iii) Redeeming, revolving, or calling instruments included in tier 2 capital other than limited life preferred stock or subordinated debt on the maturity date.

(2) The institution shall have a minimum redemption or revolvement period of 7 years for equities included in CET1 capital, a minimum no-call or redemption period of 5 years for additional tier 1 capital, and a minimum no-call, redemption, or revolvement period of 5 years for tier 2 capital.

(3) The institution shall obtain prior FCA approval before:

(i) Redesignating URE equivalents as equities that the institution may exercise its discretion to redeem other than upon dissolution or liquidation;

(ii) Removing equities or other instruments from CET1, additional tier 1, or tier 2 capital other than through repurchase, cancellation, redemption or revolvement; and

(iii) Redesignating equities included in one component of regulatory capital (CET1 capital, additional tier 1 capital, or tier 2 capital) for inclusion in another component of regulatory capital.

(4) The institution shall not exercise its discretion to revolve URE equivalents except upon dissolution or liquidation and shall not offset URE equivalents against a loan in default except as required under final order of a court of competent jurisdiction or if required under § 615.5290 in connection with a restructuring under part 617 of this chapter.

§ 615.5201 Definitions.

For the purpose of this subpart, the following definitions apply:

Allocated investment means earnings allocated but not paid in cash by a System bank to an association or other recipient.

Deferred tax assets (DTAs) means an amount of income taxes refundable or recoverable in future years as a result of temporary differences and net operating loss or tax credit carryforwards that exist at the reporting date. There are three types of DTAs and they arise from:

(1) A temporary difference that a System institution could realize through a net loss carryback;

(2) A temporary difference that a System institution could not realize through net loss carryback; and

(3) An operating loss and tax credit carryforward.

Nonagreeing association means an association that does not have an allotment agreement in effect with a Farm Credit Bank or agricultural credit bank pursuant to § 615.5207(b)(2).

Permanent capital, subject to adjustments as described in § 615.5207, includes:

(1) Current year earnings;

(2) Allocated and unallocated earnings (which, in the case of earnings allocated in any form by a System bank to any association or other recipient and retained by the bank, must be considered, in whole or in part, permanent capital of the bank or of any such association or other recipient as provided under an agreement between the bank and each such association or other recipient);

(3) All surplus;

(4) Stock issued by a System institution, except:

(i) Stock that may be retired by the holder of the stock on repayment of the holder's loan, or otherwise at the option or request of the holder;

(ii) Stock that is protected under section 4.9A of the Act or is otherwise not at risk;

(iii) Farm Credit Bank equities required to be purchased by Federal land bank associations in connection with stock issued to borrowers that is protected under section 4.9A of the Act;

(iv) Capital subject to revolvement, unless:

(A) The bylaws of the System institution clearly provide that there is no express or implied right for such capital to be retired at the end of the revolvement cycle or at any other time; and

(B) The System institution clearly states in the notice of allocation that such capital may only be retired at the sole discretion of the board of directors in accordance with statutory and regulatory requirements and that the institution does not grant any express or implied right to have such capital retired at the end of the revolvement cycle or at any other time;

(5) [Reserved]

(6) Financial assistance provided by the Farm Credit System Insurance Corporation that the FCA determines appropriate to be considered permanent capital; and

(7) Any other debt or equity instruments or other accounts the FCA has determined are appropriate to be considered permanent capital. The FCA may permit one or more System institutions to include all or a portion of such instrument, entry, or account as permanent capital, permanently or on a temporary basis, for purposes of this part.

Preferred stock means stock that is permanent capital and has dividend and/or liquidation preference over common stock.

Risk-adjusted asset base means "standardized total risk-weighted assets" as defined in § 628.2 of this chapter, adjusted in accordance with § 615.5207 and excluding the deduction in paragraph (2) of that definition for the amount of the System institution's allowance for loan losses that is not included in tier 2 capital.

Stock means stock and participation certificates.

System bank means a Farm Credit bank as defined in § 619.9140 of this chapter, which includes Farm Credit Banks, agricultural credit banks, and banks for cooperatives.

System institution means a System bank, an association of the Farm Credit System, Farm Credit Leasing Services Corporation, and their successors, and any other institution chartered by the FCA that the FCA determines should be considered a System institution for the purposes of this subpart.

Term preferred stock means preferred stock with an original maturity of at least 5 years and on which, if cumulative, the board of directors has the option to defer dividends, provided that, at the beginning of each of the last 5 years of the term of the stock, the amount that is eligible to be counted as permanent capital is reduced by 20 percent of the original amount of the stock (net of redemptions).

■ 10. Sections 615.5206, 615.5207, and 615.5208 are revised to read as follows:

§ 615.5206 Permanent capital ratio computation.

(a) The System institution's permanent capital ratio is determined on the basis of the financial statements of the System institution prepared in accordance with generally accepted accounting principles.

(b) The System institution's asset base and permanent capital are computed using average daily balances for the most recent 3 months.

(c) The System institution's permanent capital ratio is calculated by dividing the System institution's permanent capital, adjusted in accordance with § 615.5207 (the numerator), by the risk-adjusted asset base (the denominator) as defined in § 615.5201, to derive a ratio expressed as a percentage.

§ 615.5207 Capital adjustments and associated reductions to assets.

For the purpose of computing the System institution's permanent capital ratio, the following adjustments must be made prior to assigning assets to risk-weight categories and computing the ratio:

(a) Where two System institutions have stock investments in each other, such reciprocal holdings must be eliminated to the extent of the offset. If the investments are equal in amount, each System institution must deduct from its assets and its permanent capital an amount equal to the investment. If the investments are not equal in amount, each System institution must deduct from its permanent capital and its assets an amount equal to the smaller investment. The elimination of reciprocal holdings required by this paragraph must be made prior to making the other adjustments required by this section.

(b) Where an association has an equity investment in a System bank, the double counting of capital is eliminated in the following manner:

(1) For a purchased investment, each association must deduct its investment in a System bank from its permanent capital. Each System bank will consider all purchased stock investments as its permanent capital.

(2) For an allocated investment, each System bank and each of its affiliated associations may enter into an agreement that specifies, for computing permanent capital only, a dollar amount and/or percentage allotment of the association's allocated investment between the bank and the association. Section 615.5208 provides conditions for allotment agreements or defines allotments in the absence of such agreements.

(c) A Farm Credit Bank or agricultural credit bank and a recipient, other than an affiliated association, of allocated earnings from such bank may enter into an agreement specifying a dollar amount and/or percentage allotment of the recipient's allocated earnings in the bank between the bank and the recipient. Such agreement must comply with § 615.5208, except that, in the absence of an agreement, the allocated investment must be allotted 100 percent to the allocating bank and 0 percent to the recipient. All equities of the bank that are purchased by a recipient are considered as permanent capital of the issuing bank.

(d) A bank for cooperatives and a recipient of allocated earnings from such bank may enter into an agreement specifying a dollar amount and/or percentage allotment of the recipient's allocated earnings in the bank between the bank and the recipient. Such agreement must comply with § 615.5208, except that, in the absence of an agreement, the allocated investment must be allotted 100 percent to the allocating bank and 0 percent to the recipient. All equities of a bank that are purchased by a recipient shall be considered as permanent capital of the issuing bank.

(e) Where a System institution has an equity investment in another System institution to capitalize a loan participation interest, the investing System institution must deduct from its permanent capital an amount equal to its investment in the participating System institution.

(f) Each System institution must deduct from permanent capital any equity investment in a service corporation chartered under section 4.25 of the Act or the Funding Corporation chartered under section 4.9 of the Act.

(g) Each System institution must deduct from its permanent capital an amount equal to all goodwill, whenever acquired.

(h) Each System institution must deduct from its risk-adjusted asset base any item deducted from permanent capital under this section.

(i) Where a System bank and an association have an enforceable written agreement to share losses on specifically identified assets on a predetermined quantifiable basis, such assets must be counted in each System institution's risk-adjusted asset base in the same proportion as the System institutions have agreed to share the loss.

(j) The permanent capital of a System institution must exclude any accumulated other comprehensive income (loss) as reported under GAAP.

(k) For purposes of calculating capital ratios under this part, deferred-tax assets are subject to the conditions, limitations, and restrictions described in § 628.22(a)(3) of this chapter.

(l) [Reserved]

§ 615.5208 Allotment of allocated investments.

(a) The following conditions apply to agreements that a System bank enters into with an affiliated association pursuant to § 615.5207(b)(2):

(1) The agreement must be for a term of 1 year or longer.

(2) The agreement must be entered into on or before its effective date.

(3) The agreement may be amended according to its terms, but no more frequently than annually except in the event that a party to the agreement is merged or reorganized.

(4) On or before the effective date of the agreement, a certified copy of the agreement, and any amendments thereto, must be sent to the field office of the Farm Credit Administration responsible for examining the System institution. A copy must also be sent within 30 calendar days of adoption to the bank's other affiliated associations.

(5) Unless the parties otherwise agree, if the System bank and the association have not entered into a new agreement on or before the expiration of an existing agreement, the existing agreement will automatically be extended for another 12 months, unless either party notifies the Farm Credit Administration in writing of its objection to the extension prior to the expiration of the existing agreement.

(b) In the absence of an agreement between a System bank and one or more associations, or in the event that an agreement expires and at least one party has timely objected to the continuation of the terms of its agreement, the following formula applies with respect to the allocated investments held by those associations with which there is no agreement (nonagreeing associations), and does not apply to the allocated investments held by those associations with which the bank has an agreement (agreeing associations):

(1) The allotment formula must be calculated annually.

(2) The permanent capital ratio of the System bank must be computed as of the date that the existing agreement terminates, using a 3-month average daily balance, excluding the allocated investment from nonagreeing associations but including any allocated investments of agreeing associations that are allotted to the bank under applicable allocation agreements. The permanent capital ratio of each nonagreeing association must be computed as of the same date using a 3-month average daily balance, and must be computed excluding its allocated investment in the bank.

(3) If the permanent capital ratio of the System bank calculated in accordance with paragraph (b)(2) of this section is 7 percent or above, the allocated investment of each nonagreeing association whose permanent capital ratio calculated in accordance with paragraph (b)(2) of this section is 7 percent or above must be allotted 50 percent to the bank and 50 percent to the association.

(4) If the permanent capital ratio of the System bank calculated in accordance with paragraph (b)(2) of this section is 7 percent or above, the allocated investment of each nonagreeing association whose capital ratio is below 7 percent must be allotted to the association until the association's capital ratio reaches 7 percent or until all of the investment is allotted to the association, whichever occurs first. Any remaining unallotted allocated investment must be allotted 50 percent to the bank and 50 percent to the association.

(5) If the permanent capital ratio of the System bank calculated in accordance with paragraph (b)(2) of this section is less than 7 percent, the amount of additional capital needed by the bank to reach a permanent capital ratio of 7 percent must be determined, and an amount of the allocated investment of each nonagreeing association must be allotted to the System bank, as follows:

(i) If the total of the allocated investments of all nonagreeing associations is greater than the additional capital needed by the bank, the allocated investment of each nonagreeing association must be multiplied by a fraction whose numerator is the amount of capital needed by the bank and whose denominator is the total amount of allocated investments of the nonagreeing associations, and such amount must be allotted to the bank. Next, if the permanent capital ratio of any nonagreeing association is less than 7 percent, a sufficient amount of unallotted allocated investment must then be allotted to each nonagreeing association, as necessary, to increase its permanent capital ratio to 7 percent, or until all such remaining investment is allotted to the association, whichever occurs first. Any unallotted allocated investment still remaining must be allotted 50 percent to the bank and 50 percent to the nonagreeing association.

(ii) If the additional capital needed by the bank is greater than the total of the allocated investments of the nonagreeing associations, all of the remaining allocated investments of the nonagreeing associations must be allotted to the bank.

§§ 615.5209, 615.5210, 615.5211, and 615.5212 [Removed and reserved]

■ 11. Sections 615.5209, 615.5210, 615.5211, and 615.5212 are removed and reserved.

■ 12. Section 615.5220 is revised to read as follows:

§ 615.5220 Capitalization bylaws.

(a) The board of directors of each System bank and association shall, pursuant to section 4.3A of the Farm Credit Act of 1971 (Act), adopt capitalization bylaws, subject to the approval of its voting shareholders, that set forth:

(1) Classes of equities and the manner in which they shall be issued, transferred, converted and retired;

(2) For each class of equities, a description of the class(es) of persons to whom such stock may be issued, voting rights, dividend rights and preferences, and priority upon liquidation, including rights, if any, to share in the distribution of the residual estate;

(3) The number of shares and par value of equities authorized to be issued for each class of equities. However, the bylaws need not state a number or value limit for these equities:

(i) Equities that are required to be purchased as a condition of obtaining a loan, lease, or related service.

(ii) Non-voting stock resulting from the conversion of voting stock due to repayment of a loan.

(iii) Non-voting equities that are issued to an association's funding bank in conjunction with any agreement for a transfer of capital between the association and the bank.

(iv) Equities resulting from the distribution of earnings.

(4) For Farm Credit Banks, agricultural credit banks (with respect to loans other than to cooperatives), and associations, the percentage or dollar amount of equity investment (which may be expressed as a range within which the board of directors may from time to time determine the requirement) that will be required to be purchased as a condition for obtaining a loan, which amount shall be not less than 2 percent of the loan amount or $1,000, whichever is less;

(5) For banks for cooperatives and agricultural credit banks (with respect to loans to cooperatives), the percentage or dollar amount of equity or guaranty fund investment (which may be expressed as a range within which the board may from time to time determine the requirement) that serves as a target level of investment in the bank for patronage-sourced business, which amount shall not be less than, 2 percent of the loan amount or $1,000, whichever is less;

(6) The manner in which equities will be retired, including a provision stating that equities other than those protected under section 4.9A of the Act are retireable at the sole discretion of the board, provided minimum capital adequacy standards established in subpart H of this part, part 628 of this chapter, and the capital requirements established by the board of directors of the System institution, are met;

(7) The manner in which earnings will be allocated and distributed, including the basis on which patronage will be paid, which shall be in accord with cooperative principles; and

(8) For System banks, the manner in which the capitalization requirements of the Farm Credit bank shall be allocated and equalized from time to time among its owners.

(b) The board of directors of each service corporation (including the Farm Credit Leasing Services Corporation) shall adopt capitalization bylaws, subject to the approval of its voting shareholders, that set forth the requirements of paragraphs (a)(1), (2), and (3) of this section to the extent applicable. Such bylaws shall also set forth the manner in which equities will be retired and the manner in which earnings will be distributed.

■ 13. Section 615.5240 is revised to read as follows:

§ 615.5240 Regulatory capital requirements.

(a) The capitalization bylaws shall enable the institution to meet the capital adequacy standards established under subpart H of this part, part 628 of this chapter, and the capital requirements established by the board of directors of the System institution.

(b) In order to qualify as permanent capital, equities issued under the bylaws must meet the following requirements:

(1) Retirement must be solely at the discretion of the board of directors and not upon a date certain (other than the original maturity date of preferred stock) or upon the happening of any event, such as repayment of the loan, and not pursuant to any automatic retirement or revolvement plan;

(2) Retirement must be at not more than book value;

(3) The institution must have made the disclosures required by this subpart;

(4) For common stock and participation certificates, dividends must be noncumulative and payable only at the discretion of the board; and

(5) For cumulative preferred stock, the board of directors must have discretion to defer payment of dividends.

■ 14. Sections 615.5250 and 615.5255 are revised to read as follows:

§ 615.5250 Disclosure requirements for sales of borrower stock.

(a) For sales of borrower stock, which for this subpart means equities purchased as a condition for obtaining a loan, a System institution must provide a prospective borrower with the following documents prior to loan closing:

(1) The institution's most recent annual report filed under part 620 of this chapter;

(2) The institution's most recent quarterly report filed under part 620 of this chapter, if more recent than the annual report;

(3) A copy of the institution's capitalization bylaws; and

(4) A written description of the terms and conditions under which the equity is issued. In addition to specific terms and conditions, the description must disclose:

(i) That the equity is an at-risk investment and not a compensating balance;

(ii) That the equity is retireable only at the discretion of the board of directors consistent with the institution's bylaws and only if minimum capital standards established under subpart H of this part and part 628 of this chapter are met and that such retirement may also require the approval of the FCA;

(iii) Whether the institution presently meets its minimum capital standards established under subpart H of this part and part 628 of this chapter;

(iv) Whether the institution knows of any reason the institution may not meet its capital standards on the next earnings distribution date; and

(v) The rights, if any, to share in patronage payments.

(b) Notwithstanding the provisions of paragraph (a) of this section, no materials previously provided to a purchaser (except the disclosures required by paragraph (a)(4) of this section) need be provided again unless the purchaser requests such materials.

§ 615.5255 Disclosure and review requirements for sales of other equities.

(a) A bank, association, or service corporation must submit a proposed disclosure statement to the Farm Credit Administration (FCA) for review and clearance prior to the proposed sale of any other equities, which for this subpart means equities not purchased as a condition for obtaining a loan.

(b) An institution may not offer to sell other equities until a disclosure statement is reviewed and cleared by the FCA.

(c) A disclosure statement must include:

(1) All of the information required by parts 620 and 628 of this chapter in the annual report to shareholders as of a date within 135 days of the proposed sale. An institution may satisfy this requirement by referring to its most recent annual report to shareholders and the most recent quarterly report filed with the FCA, provided such reports contain the required information;

(2) The information required by § 615.5250(a)(3) and (4); and

(3) A discussion of the intended use of the sale proceeds.

(d) An institution is not required to provide the materials identified in paragraphs (c)(1) and (2) of this section to a purchaser who previously received them unless the purchaser requests it.

(e) For any class of stock where each purchaser and each subsequent transferee acquires at least $250,000 of the stock and meets the definition of "accredited investor" or "qualified institutional buyer" contained in 17 CFR 230.501 and 230.144A, a disclosure statement submitted pursuant to this section is deemed reviewed and cleared by the FCA and an institution may treat stock that meets all requirements of this part as permanent capital for the purpose of meeting the minimum permanent capital standards established under subpart H of this part, unless the FCA notifies the institution to the contrary within 30 days of receipt of a complete disclosure statement submission. A complete disclosure statement submission includes the proposed disclosure statement plus any additional materials requested by the FCA.

(f) For all other issuances, a disclosure statement submitted pursuant to this section is deemed cleared by the FCA, and an institution may treat stock that meets all requirements of this part as permanent capital for the purpose of meeting the minimum permanent capital standards established under subpart H unless the FCA notifies the institution to the contrary within 60 days of receipt of a complete disclosure statement submission. A complete disclosure statement submission includes the proposed disclosure statement plus any additional materials requested by the FCA.

(g) Upon request, the FCA will inform the institution how it will treat the proposed issuance for other regulatory capital ratios or computations.

(h) No institution, officer, director, employee, or agent shall, in connection with the sale of equities, make any disclosure, through a disclosure statement or otherwise, that is inaccurate or misleading, or omit to make any statement needed to prevent other disclosures from being misleading.

(i) Each bank and association must establish a method to disclose and make information on insider preferred stock purchases and retirements readily available to the public. At a minimum, each institution offering preferred stock must make this information available upon request.

(j) The requirements of this section do not apply to the sale of Farm Credit System institution equities to:

(1) Other Farm Credit System institutions;

(2) Other financing institutions in connection with a lending or discount relationship; or

(3) Non-Farm Credit System lenders that purchase equities in connection with a loan participation transaction.

(k) In addition to the requirements of this section, each institution is responsible for ensuring its compliance with all applicable Federal and state securities laws.

■ 15. Section 615.5270 is revised to read as follows:

§ 615.5270 Retirement of other equities.

(a) Equities other than eligible borrower stock shall be retired at not more than their book value.

(b) Subject to the redemption restrictions in part 628 of this chapter, no equities shall be retired, except pursuant to §§ 615.5280 and 615.5290 or term stock at its stated maturity, unless after retirement the institution would continue to meet the minimum permanent capital standards established under subpart H of this part, part 628 of this chapter, and the capital requirements established by the board of directors of the System institution.

(c) A System bank, association, or service corporation board of directors may delegate authority to retire at-risk stock to institution management if:

(1) The board has determined that the institution's capital position is adequate;

(2) All retirements are in accordance with applicable provisions of part 628 of this chapter and the institution's capital adequacy plan or capital restoration plan;

(3) After any retirements, the institution's permanent capital ratio will be in excess of 9 percent, its capital conservation buffer set forth in § 628.11 of this chapter will be above 2.5 percent, and its leverage buffer set forth in § 628.11 of this chapter will be above 1.0 percent;

(4) The institution will continue to satisfy all applicable regulatory capital standards after any retirements; and

(5) Management reports the aggregate amount and net effect of stock purchases and retirements to the board of directors each quarter.

(d) Each board of directors of a System bank, association, or service corporation that issues preferred stock must adopt a written policy covering the retirement of preferred stock that complies with this paragraph and part 628 of this chapter. The policy must, at a minimum:

(1) Establish any delegations of authority to retire preferred stock and the conditions of delegation, which must meet the requirements of paragraph (c) of this section and include minimum levels for regulatory capital standards as applicable and commensurate with the volatility of the preferred stock.

(2) Identify limitations on the amount of stock that may be retired during a single quarterly (or shorter) time period;

(3) Ensure that all stockholder requests for retirement are treated fairly and equitably;

(4) Prohibit any insider, including institution officers, directors, employees, or agents, from retiring any preferred stock in advance of the release of material non-public information concerning the institution to other stockholders; and

(5) Establish when insiders may retire their preferred stock.

(e) The institution's board must review its policy at least annually to ensure that it continues to be appropriate for the institution's current financial condition and consistent with its long-term goals established in its capital adequacy plan.

■ 16. Section 615.5290 is revised to read as follows:

§ 615.5290 Retirement of capital stock and participation certificates in event of restructuring.

(a) If a Farm Credit Bank or agricultural credit bank forgives and writes off, under § 617.7415 of this chapter, any of the principal outstanding on a loan made to any borrower, where appropriate the Federal land bank association of which the borrower is a member and stockholder shall cancel the same dollar amount of borrower stock held by the borrower in respect of the loan, up to the total amount of such stock, and to the extent provided for in the bylaws of the Bank relating to its capitalization, the Farm Credit Bank or agricultural credit bank shall retire an equal amount of stock owned by the Federal land bank association.

(b) If an association forgives and writes off, under § 617.7415 of this chapter, any of the principal outstanding on a loan made to any borrower, the association shall cancel the same dollar amount of borrower stock held by the borrower in respect of the loan, up to the total amount of such loan.

(c) Notwithstanding paragraphs (a) and (b) of this section, the borrower shall be entitled to retain at least one share of stock to maintain the borrower's membership and voting interest.

■ 17. Section 615.5295 is amended by revising paragraph (c) to read as follows:

§ 615.5295 Payment of dividends.

* * * * *

(c) Each System bank, association, and service corporation must exclude any accrued but unpaid dividends from regulatory capital computations under this part and part 628 of this chapter.

Subpart K [Removed and reserved]

■ 18. Subpart K, consisting of §§ 615.5301, 615.5330, 615.5335, and 615.5336, is removed and reserved.

■ 19. Section 615.5350 is amended by revising paragraph (a) to read as follows:

§ 615.5350 General—Applicability.

(a) The rules and procedures specified in this subpart are applicable to a proceeding to establish required minimum capital ratios that would otherwise be applicable to an institution under §§ 615.5205 and 628.10 of this chapter. The Farm Credit Administration is authorized to establish such minimum capital requirements for an institution as the Farm Credit Administration, in its discretion, deems to be necessary or appropriate in light of the particular circumstances of the institution. Proceedings under this subpart also may be initiated to require an institution having capital ratios greater than those set forth in § 615.5205 or § 628.10 of this chapter to continue to maintain those higher ratios.

* * * * *

■ 20. Section 615.5352 is amended by revising paragraph (a) to read as follows:

§ 615.5352 Procedures.

(a) *Notice.* When the Farm Credit Administration determines that minimum capital ratios greater than those set forth in § 615.5205 or § 628.10 of this chapter are necessary or appropriate for a particular institution, the Farm Credit Administration will notify the institution in writing of the proposed minimum capital ratios and the date by which they should be reached (if applicable) and will provide an explanation of why the ratios proposed are considered necessary or appropriate for the institution.

* * * * *

■ 21. Section 615.5354 is revised to read as follows:

§ 615.5354 Enforcement.

An institution that does not have or maintain the minimum capital ratios applicable to it, whether required in subpart H of this part or part 628 of this chapter, in a decision pursuant to this subpart, in a written agreement or temporary or final order under part C of title V of the Act, or in a condition for approval of an application, or an institution that has failed to submit or comply with an acceptable plan to attain those ratios, will be subject to such administrative action or sanctions as the Farm Credit Administration considers appropriate. These sanctions may include the issuance of a capital directive pursuant to subpart M of this part or other enforcement action, assessment of civil money penalties, and/or the denial or condition of applications.

■ 22. Section 615.5355 is amended by revising paragraph (a) introductory text to read as follows:

§ 615.5355 Purpose and scope.

(a) This subpart is applicable to proceedings by the Farm Credit Administration to issue a capital directive under sections 4.3(b) and 4.3A(e) of the Act. A capital directive is an order issued to an institution that does not have or maintain capital at or greater than the minimum ratios set forth in § 615.5205 or § 628.10 of this chapter; or established for the institution under subpart L of this part, by a written agreement under part C of title V of the Act, or as a condition for approval of an application. A capital directive may order the institution to:

* * * * *

PART 620—DISCLOSURE TO SHAREHOLDERS

■ 23. The authority citation for part 620 continues to read as follows:

Authority: Secs. 4.3, 4.3A, 4.19, 5.9, 5.17, 5.19 of the Farm Credit Act (12 U.S.C. 2154, 2154a, 2207, 2243, 2252, 2254); sec. 424 of Pub. L. 100–233, 101 Stat. 1568, 1656; sec. 514 of Pub. L. 102–552, 106 Stat. 4102.

■ 24. Section 620.5 is amended by revising paragraphs (d)(1)(ix), (f)(2)(ii) through (iv), (f)(3)(ii) and (iii), and (g)(4)(ii) and adding paragraphs (f)(2)(v), (f)(3)(iv), and (f)(4) to read as follows:

§ 620.5 Contents of the annual report to shareholders.

* * * * *

(d) * * *

(1) * * *

(ix) The statutory and regulatory restrictions regarding retirement of stock and distribution of earnings pursuant to § 615.5215 of this chapter, and any requirements to add capital under a plan approved by the Farm Credit Administration pursuant to § 615.5350, § 615.5351, § 615.5353, § 615.5357, or § 628.301 of this chapter.

* * * * *

(f) * * *

(2) * * *

(ii) CET1 capital ratio.

(iii) Tier 1 capital ratio.

(iv) Total capital ratio.

(v) Tier 1 leverage ratio.

(3) * * *

(ii) CET1 capital ratio.

(iii) Tier 1 capital ratio.

(iv) Total capital ratio.

(4) The annual report for each fiscal year ending in 2017 through 2021 shall also include in comparative columnar form for each fiscal year ending in 2012 through 2016, the following ratios:

(i) Core surplus ratio.

(ii) Total surplus ratio.

(iii) For banks only, net collateral ratio.

(iv) Tier 1 leverage ratio.

(g) * * *

(4) * * *

(ii) Describe any material trends or changes in the mix and cost of debt and capital resources. The discussion shall consider changes in permanent capital, CET1 capital, tier 1 capital, total capital, the tier 1 leverage ratio, debt, and any off-balance-sheet financial arrangements.

* * * * *

■ 25. Section 620.17 is revised to read as follows:

§ 620.17 Special notice provisions for events related to noncompliance with minimum regulatory capital ratios.

(a) For purposes of this section, "regulatory capital ratios" include the capital ratios specified in § 628.10 of this chapter and the permanent capital standard prescribed under § 615.5205 of this chapter.

(b) When a Farm Credit bank or association determines that it is not in compliance with one or more applicable minimum regulatory capital ratios, that institution must prepare and provide to its shareholders and the FCA a notice stating that the institution has initially determined it is not in compliance with the minimum regulatory capital ratio or ratios. Such notice must be given within 30 days following the month end.

(c) When notice is given under paragraph (b) of this section, the institution must also notify its shareholders and the FCA when the regulatory capital ratio or ratios that are the subject of such notice decrease by one half of 1 percent or more from the level reported in the original notice, or from that reported in a subsequent notice provided under this paragraph (c). This notice must be given within 45 days following the end of every quarter at which the institution's regulatory capital ratio or ratios decrease as specified.

(d) Each institution required to prepare a notice under paragraph (b) or (c) of this section shall provide the notice to shareholders or publish it in any publication with circulation wide enough to be reasonably assured that all of the institution's shareholders have access to the information in a timely manner. The information required to be included in this notice must be conspicuous, easily understandable, and not misleading.

(e) A notice, at a minimum, shall include:

(1) A statement that:

(i) Briefly describes the minimum regulatory capital ratios established by the FCA and the notice requirement of paragraph (b) of this section;

(ii) Indicates the institution's current level of capital; and

(iii) Notifies shareholders that the institution's capital is below the FCA minimum regulatory capital ratio or ratios.

(2) A statement of the effect that noncompliance has had on the institution and its shareholders, including whether the institution is currently prohibited by statute or regulation from retiring stock or distributing earnings or whether the FCA has issued a capital directive or other enforcement action to the institution.

(3) A complete description of any event(s) that may have significantly contributed to the institution's noncompliance with the minimum regulatory capital ratio or ratios.

(4) A statement that the institution is required by regulation to provide another notice to shareholders within 45 days following the end of any subsequent quarter at which the regulatory capital ratio or ratios decrease by one half of 1 percent or more from the level reported in the notice.

PART 624—MARGIN AND CAPITAL REQUIREMENTS FOR COVERED SWAP ENTITIES

■ 26. The authority citation for part 624 continues to read as follows:

Authority: 7 U.S.C. 6s(e), 15 U.S.C. 78o–10(e), 12 U.S.C. 2154, 12 U.S.C. 2243, 12 U.S.C. 2252, and 12 U.S.C. 2279bb–1.

■ 27. Section 624.12 is amended by revising paragraph (b) to read as follows:

§ 624.12 Capital.

* * * * *

(b) In the case of any Farm Credit System institution other than the Federal Agricultural Mortgage Corporation, the capital regulations set forth in parts 615 and 628 of this chapter.

PART 627—TITLE V CONSERVATORS, RECEIVERS, AND VOLUNTARY LIQUIDATIONS

■ 28. The authority citation for part 627 continues to read as follows:

Authority: Secs. 4.2, 5.9, 5.17, 5.51, 5.58, 5.61 of the Farm Credit Act (12 U.S.C. 2183, 2243, 2244, 2252, 2277a, 2277a–7, 2277a–10).

§ 627.2710 [Amended]

■ 29. Section 627.2710 is amended by removing and reserving paragraphs (b)(3)(i) and (iv).

■ 30. Part 628 is added to read as follows:

PART 628—CAPITAL ADEQUACY OF SYSTEM INSTITUTIONS

Subpart A—General Provisions

Sec.
628.1 Purpose, applicability, and reservations of authority.
628.2 Definitions.
628.3 Operational requirements for certain exposures.
628.4–628.9 [Reserved]

Subpart B—Capital Ratio Requirements and Buffers

628.10 Minimum capital requirements.
628.11 Capital buffer amounts.
628.12–628.19 [Reserved]

Subpart C—Definition of Capital

628.20 Capital components and eligibility criteria for tier 1 and tier 2 capital instruments.
628.21 [Reserved]
628.22 Regulatory capital adjustments and deductions.
628.23 Limit on inclusion of third-party capital in total (tier 1 and tier 2) capital.
628.24–628.29 [Reserved]

Subpart D—Risk-Weighted Assets—Standardized Approach

628.30 Applicability.

Risk-Weighted Assets for General Credit Risk

628.31 Mechanics for calculating risk-weighted assets for general credit risk.
628.32 General risk weights.
628.33 Off-balance sheet exposures.
628.34 OTC derivative contracts.
628.35 Cleared transactions.
628.36 Guarantees and credit derivatives: substitution treatment.
628.37 Collateralized transactions.

Risk-Weighted Assets for Unsettled Transactions

628.38 Unsettled transactions.
628.39 through 628.40 [Reserved]

Risk-Weighted Assets for Securitization Exposures

628.41 Operational requirements for securitization exposures.
628.42 Risk-weighted assets for securitization exposures.
628.43 Simplified supervisory formula approach (SSFA) and the gross-up approach.
628.44 Securitization exposures to which the SSFA and gross-up approach do not apply.
628.45 Recognition of credit risk mitigants for securitization exposures.
628.46–628.50 [Reserved]

Risk-Weighted Assets for Equity Exposures

628.51 Introduction and exposure measurement.
628.52 Simple risk-weight approach (SRWA).
628.53 Equity exposures to investment funds.
628.54 through 628.60 [Reserved]

Disclosures

628.61 Purpose and scope.
628.62 Disclosure requirements.
628.63 Disclosures.
628.64 through 628.99 [Reserved]

Subpart E—[Reserved]

Subpart F—[Reserved]

Subpart G—Transition Provisions

628.300 Transitions.
628.301 Initial compliance and reporting requirements.

Authority: Secs. 1.5, 1.7, 1.10, 1.11, 1.12, 2.2, 2.3, 2.4, 2.5, 2.12, 3.1, 3.7, 3.11, 3.25, 4.3, 4.3A, 4.9, 4.14B, 4.25, 5.9, 5.17, 6.20, 6.26, 8.0, 8.3, 8.4, 8.6, 8.7, 8.8, 8.10, 8.12 of the Farm Credit Act (12 U.S.C. 2013, 2015, 2018, 2019, 2020, 2073, 2074, 2075, 2076, 2093, 2122, 2128, 2132, 2146, 2154, 2154a, 2160, 2202b, 2211, 2243, 2252, 2278b, 2278b–6, 2279aa, 2279aa–3, 2279aa–4, 2279aa–6, 2279aa–7, 2279aa–8, 2279aa–10, 2279aa–12); sec. 301(a), Pub. L. 100–233, 101 Stat. 1568, 1608; sec. 939A, Pub. L. 111–203, 124 Stat. 1326, 1887 (15 U.S.C. 78o–7 note).

Subpart A—General Provisions

§ 628.1 Purpose, applicability, and reservations of authority.

(a) *Purpose.* This part establishes minimum capital requirements and overall capital adequacy standards for System institutions. This part includes methodologies for calculating minimum capital requirements, public disclosure requirements related to the capital requirements, and transition provisions for the application of this part.

(b) *Limitation of authority.* Nothing in this part limits the authority of FCA to take action under other provisions of law, including action to address unsafe or unsound practices or conditions, deficient capital levels, or violations of law or regulation under part C of title V of the Farm Credit Act.

(c) *Applicability.* Subject to the requirements in paragraph (d) of this section:

(1) *Minimum capital requirements and overall capital adequacy standards.* Each System institution must calculate its minimum capital requirements and meet the overall capital adequacy standards in subpart B of this part.

(2) *Regulatory capital.* Each System institution must calculate its regulatory capital in accordance with subpart C of this part.

(3) *Risk-weighted assets.* (i) Each System institution must use the methodologies in subpart D of this part to calculate total risk-weighted assets.

(ii) [Reserved]

(4) *Disclosures.* (i) All System banks must make the public disclosures described in subpart D of this part.

(ii) [Reserved]

(iii) [Reserved]

(d) *Reservation of authority*—(1) *Additional capital in the aggregate.* FCA may require a System institution to hold an amount of regulatory capital greater than otherwise required under this part if FCA determines that the System institution's capital requirements under this part are not commensurate with the System institution's credit, market, operational, or other risks according to part 615, subparts L and M, of this chapter.

(2) *Regulatory capital elements.* (i) If FCA determines that a particular common equity tier 1 (CET1), additional tier 1 (AT1), or tier 2 capital element has characteristics or terms that diminish its permanence or its ability to absorb losses, or otherwise present safety and soundness concerns, FCA may require the System institution to exclude all or a portion of such element from CET1 capital, AT1 capital, or tier 2 capital, as appropriate.

(ii) Notwithstanding the criteria for regulatory capital instruments set forth in subpart C of this part, FCA may find that a capital element may be included in a System institution's CET1 capital, AT1 capital, or tier 2 capital on a permanent or temporary basis consistent with the loss absorption capacity of the element and in accordance with § 628.20(e).

(3) *Risk-weighted asset amounts.* If FCA determines that the risk-weighted asset amount calculated under this part by the System institution for one or more exposures is not commensurate with the risks associated with those exposures, FCA may require the System institution to assign a different risk-weighted asset amount to the exposure(s) or to deduct the amount of the exposure(s) from its regulatory capital.

(4) *Total leverage.* If FCA determines that the leverage exposure amount, or the amount reflected in the System institution's reported average total consolidated assets, for a balance sheet exposure calculated by a System institution under § 628.10 is inappropriate for the exposure(s) or the circumstances of the System institution, FCA may require the System institution to adjust this exposure amount in the numerator and the denominator for purposes of the leverage ratio calculations.

(5) [Reserved]

(6) *Other reservation of authority.* With respect to any deduction or limitation required under this part, FCA may require a different deduction or limitation, provided that such alternative deduction or limitation is commensurate with the System institution's risk and consistent with safety and soundness.

(e) *Notice and response procedures.* In making a determination under this section, FCA will apply notice and response procedures in the same manner as the notice and response procedures in § 615.5352 of this chapter.

(f) [Reserved]

§ 628.2 Definitions.

As used in this part:

Additional tier 1 capital (AT1) is defined in § 628.20(c).

Allocated equities means stock or surplus representing a patronage payment to a member-borrower that a System institution has retained for the benefit of its membership.[1] Allocated equities include qualified allocated equities and nonqualified allocated equities. Allocated equities are redeemable at the System institution board's discretion. Allocated equities contain no voting rights and are generally subordinated to borrower stock in receivership, insolvency, liquidation, or similar proceeding.

Allowances for loan losses (ALL) means valuation allowances that have been established through a charge against earnings to cover estimated credit losses on loans, lease financing receivables, or other extensions of credit as determined in accordance with generally accepted accounting principles (GAAP). For purposes of this part, ALL includes allowances that have been established through a charge against earnings to cover estimated credit losses associated with off-balance sheet credit exposures as determined in accordance with GAAP.

Bank holding company means a bank holding company as defined in section 2 of the Bank Holding Company Act.

Bank Holding Company Act means the Bank Holding Company Act of 1956, as amended (12 U.S.C. 1841 *et seq.*).

Bankruptcy remote means, with respect to an entity or asset, that the entity or asset would be excluded from an insolvent entity's estate in receivership, insolvency, liquidation, or similar proceeding.

Borrower stock means the capital investment a borrower holds in a System institution in connection with a loan.

Call Report means reports of condition and performance, as described in subpart D of part 621 of this chapter.

Carrying value means, with respect to an asset, the value of the asset on the balance sheet of the System institution, determined in accordance with GAAP.

Central counterparty (CCP) means a counterparty (for example, a clearinghouse) that facilitates trades between counterparties in one or more financial markets by either guaranteeing trades or novating contracts.

CFTC means the U.S. Commodity Futures Trading Commission.

Clean-up call means a contractual provision that permits an originating System institution or servicer to call securitization exposures before their stated maturity or call date.

Cleared transaction means an exposure associated with an outstanding derivative contract or repo-style transaction that a System institution or clearing member has entered into with a central counterparty (that is, a transaction that a central counterparty has accepted).

(1) The following transactions are cleared transactions:

(i) [Reserved]

(ii) [Reserved]

(iii) A transaction between a clearing member client System institution and a clearing member where the clearing member acts as a financial intermediary on behalf of the clearing member client and enters into an offsetting transaction with a CCP, provided that the requirements set forth in § 628.3(a) are met; or

(iv) A transaction between a clearing member client System institution and a CCP where a clearing member guarantees the performance of the clearing member client System institution to the CCP and the transaction meets the requirements of § 628.3(a)(2) and (3).

(2) [Reserved]

Clearing member means a member of, or direct participant in, a CCP that is entitled to enter into transactions with the CCP.

Clearing member client means a party to a cleared transaction associated with a CCP in which a clearing member either acts as a financial intermediary with respect to the party or guarantees the performance of the party to the CCP.

Collateral agreement means a legal contract that specifies the time when, and circumstances under which, a counterparty is required to pledge collateral to a System institution for a single financial contract or for all financial contracts in a netting set and confers upon the System institution a perfected, first-priority security interest (notwithstanding the prior security interest of any custodial agent), or the legal equivalent thereof, in the collateral posted by the counterparty under the agreement. This security interest must provide the System institution with a right to close-out the financial positions and liquidate the collateral upon an event of default of, or failure to perform by, the counterparty under the collateral agreement. A contract would not satisfy this requirement if the System institution's exercise of rights under the agreement may be stayed or avoided under applicable law in the relevant jurisdictions, other than:

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[1] System institutions as cooperatives are required to send borrowers a written notice of allocation specifying the amount of patronage payments retained as equity pursuant to the Internal Revenue Code section 1388.

(1) In receivership, conservatorship, or resolution under the Federal Deposit Insurance Act, title II of the Dodd-Frank Act, or under any similar insolvency law applicable to GSEs, or laws of foreign jurisdictions that are substantially similar to the U.S. laws referenced in this paragraph (1) in order to facilitate the orderly resolution of the defaulting counterparty; or

(2) Where the agreement is subject by its terms to any of the laws referenced in paragraph (1) of this definition.

Commitment means any legally binding arrangement that obligates a System institution to extend credit or to purchase assets.

Commodity derivative contract means a commodity-linked swap, purchased commodity-linked option, forward commodity-linked contract, or any other instrument linked to commodities that gives rise to similar counterparty credit risks.

Commodity Exchange Act means the Commodity Exchange Act of 1936 (7 U.S.C. 1 *et seq.*).

Common cooperative equity or equities means common equities in the form of member-borrower stock, participation certificates, and allocated equities issued or allocated by a System institution to its current and former members.

Common equity tier 1 capital (CET1) is defined in § 628.20(b).

Company means a corporation, partnership, limited liability company, depository institution, business trust, special purpose entity, System institution, association, or similar organization.

Corporate exposure means an exposure to a company that is not:

(1) An exposure to a sovereign, the Bank for International Settlements, the European Central Bank, the European Commission, the International Monetary Fund, a multi-lateral development bank (MDB), a depository institution, a foreign bank, a credit union, or a public sector entity (PSE);

(2) An exposure to a GSE;

(3) A residential mortgage exposure;

(4) [Reserved]

(5) [Reserved]

(6) [Reserved]

(7) A cleared transaction;

(8) [Reserved]

(9) A securitization exposure;

(10) An equity exposure; or

(11) An unsettled transaction.

Country risk classification (CRC) with respect to a sovereign, means the most recent consensus CRC published by the Organization for Economic Cooperation and Development (OECD) as of December 31st of the prior calendar year that provides a view of the likelihood that the sovereign will service its external debt.

Credit derivative means a financial contract executed under standard industry credit derivative documentation that allows one party (the protection purchaser) to transfer the credit risk of one or more exposures (reference exposure(s)) to another party (the protection provider) for a certain period of time.

Credit-enhancing interest-only strip (CEIO) means an on-balance sheet asset that, in form or in substance:

(1) Represents a contractual right to receive some or all of the interest and no more than a minimal amount of principal due on the underlying exposures of a securitization; and

(2) Exposes the holder of the CEIO to credit risk directly or indirectly associated with the underlying exposures that exceeds a pro rata share of the holder's claim on the underlying exposures, whether through subordination provisions or other credit-enhancement techniques.

Credit-enhancing representations and warranties means representations and warranties that are made or assumed in connection with a transfer of underlying exposures (including loan servicing assets) and that obligate a System institution to protect another party from losses arising from the credit risk of the underlying exposures. Credit-enhancing representations and warranties include provisions to protect a party from losses resulting from the default or nonperformance of the counterparties of the underlying exposures or from an insufficiency in the value of the collateral backing the underlying exposures. Credit-enhancing representations and warranties do not include:

(1) Early default clauses and similar warranties that permit the return of, or premium refund clauses covering, 1–4 family residential first mortgage loans that qualify for a 50-percent risk weight for a period not to exceed 120 days from the date of transfer. These warranties may cover only those loans that were originated within 1 year of the date of transfer;

(2) Premium refund clauses that cover assets guaranteed, in whole or in part, by the U.S. Government, a U.S. Government agency or a Government-sponsored enterprise (GSE), provided the premium refund clauses are for a period not to exceed 120 days from the date of transfer; or

(3) Warranties that permit the return of underlying exposures in instances of misrepresentation, fraud, or incomplete documentation.

Credit risk mitigant means collateral, a credit derivative, or a guarantee.

Credit union means an insured credit union as defined under the Federal Credit Union Act (12 U.S.C. 1752 *et seq.*).

Current exposure means, with respect to a netting set, the larger of 0 or the fair value of a transaction or portfolio of transactions within the netting set that would be lost upon default of the counterparty, assuming no recovery on the value of the transactions. Current exposure is also called replacement cost.

Current exposure methodology means the method of calculating the exposure amount for over-the-counter derivative contracts in § 628.34(a).

Custodian means a company that has legal custody of collateral provided to a CCP.

Depository institution means a depository institution as defined in section 3 of the Federal Deposit Insurance Act.

Depository institution holding company means a bank holding company or savings and loan holding company.

Derivative contract means a financial contract whose value is derived from the values of one or more underlying assets, reference rates, or indices of asset values or reference rates. Derivative contracts include interest rate derivative contracts, exchange rate derivative contracts, equity derivative contracts, commodity derivative contracts, credit derivative contracts, and any other instrument that poses similar counterparty credit risks. Derivative contracts also include unsettled securities, commodities, and foreign exchange transactions with a contractual settlement or delivery lag that is longer than the lesser of the market standard for the particular instrument or 5 business days.

Dodd-Frank Act means the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (Pub. L. 111–203, 124 Stat. 1376).

Early amortization provision means a provision in the documentation governing a securitization that, when triggered, causes investors in the securitization exposures to be repaid before the original stated maturity of the securitization exposures, unless the provision:

(1) Is triggered solely by events not directly related to the performance of the underlying exposures or the originating System institution (such as material changes in tax laws or regulations); or

(2) Leaves investors fully exposed to future draws by borrowers on the underlying exposures even after the provision is triggered.

Effective notional amount means, for an eligible guarantee or eligible credit derivative, the lesser of the contractual notional amount of the credit risk mitigant and the exposure amount of the hedged exposure, multiplied by the percentage coverage of the credit risk mitigant.

Eligible clean-up call means a clean-up call that:

(1) Is exercisable solely at the discretion of the originating System institution or servicer;

(2) Is not structured to avoid allocating losses to securitization exposures held by investors or otherwise structured to provide credit enhancement to the securitization; and

(3)(i) For a traditional securitization, is only exercisable when 10 percent or less of the principal amount of the underlying exposures or securitization exposures (determined as of the inception of the securitization) is outstanding; or

(ii) For a synthetic securitization, is only exercisable when 10 percent or less of the principal amount of the reference portfolio of underlying exposures (determined as of the inception of the securitization) is outstanding.

Eligible credit derivative means a credit derivative in the form of a credit default swap, n^{th}-to-default swap, total return swap, or any other form of credit derivative approved by the FCA, provided that:

(1) The contract meets the requirements of an eligible guarantee and has been confirmed by the protection purchaser and the protection provider;

(2) Any assignment of the contract has been confirmed by all relevant parties;

(3) If the credit derivative is a credit default swap or n^{th}-to-default swap, the contract includes the following credit events:

(i) Failure to pay any amount due under the terms of the reference exposure, subject to any applicable minimal payment threshold that is consistent with standard market practice and with a grace period that is closely in line with the grace period of the reference exposure; and

(ii) Receivership, insolvency, liquidation, conservatorship or inability of the reference exposure issuer to pay its debts, or its failure or admission in writing of its inability generally to pay its debts as they become due, and similar events;

(4) The terms and conditions dictating the manner in which the contract is to be settled are incorporated into the contract;

(5) If the contract allows for cash settlement, the contract incorporates a robust valuation process to estimate loss reliably and specifies a reasonable period for obtaining post-credit event valuations of the reference exposure;

(6) If the contract requires the protection purchaser to transfer an exposure to the protection provider at settlement, the terms of at least one of the exposures that is permitted to be transferred under the contract provide that any required consent to transfer may not be unreasonably withheld;

(7) If the credit derivative is a credit default swap or n^{th}-to-default swap, the contract clearly identifies the parties responsible for determining whether a credit event has occurred, specifies that this determination is not the sole responsibility of the protection provider, and gives the protection purchaser the right to notify the protection provider of the occurrence of a credit event; and

(8) If the credit derivative is a total return swap and the System institution records net payments received on the swap as net income, the System institution records offsetting deterioration in the value of the hedged exposure (either through reductions in fair value or by an addition to reserves).

Eligible guarantee means a guarantee from an eligible guarantor that:

(1) Is written;

(2) Is either:

(i) Unconditional; or

(ii) A contingent obligation of the U.S. Government or its agencies, the enforceability of which is dependent upon some affirmative action on the part of the beneficiary of the guarantee or a third party (for example, meeting servicing requirements);

(3) Covers all or a pro rata portion of all contractual payments of the obligated party on the reference exposure;

(4) Gives the beneficiary a direct claim against the protection provider;

(5) Is not unilaterally cancelable by the protection provider for reasons other than the breach of the contract by the beneficiary;

(6) Except for a guarantee by a sovereign, is legally enforceable against the protection provider in a jurisdiction where the protection provider has sufficient assets against which a judgment may be attached and enforced;

(7) Requires the protection provider to make payment to the beneficiary on the occurrence of a default (as defined in the guarantee) of the obligated party on the reference exposure in a timely manner without the beneficiary first having to take legal actions to pursue the obligor for payment; and

(8) Does not increase the beneficiary's cost of credit protection on the guarantee in response to deterioration in the credit quality of the reference exposure.

Eligible guarantor means:

(1) A sovereign, the Bank for International Settlements, the International Monetary Fund, the European Central Bank, the European Commission, a Federal Home Loan Bank, Federal Agricultural Mortgage Corporation (Farmer Mac), a multilateral development bank (MDB), a depository institution, a bank holding company, a savings and loan holding company, a credit union, a foreign bank, or a qualifying central counterparty; or

(2) An entity (other than a special purpose entity):

(i) That at the time the guarantee is issued or anytime thereafter, has issued and outstanding an unsecured debt security without credit enhancement that is investment grade;

(ii) Whose creditworthiness is not positively correlated with the credit risk of the exposures for which it has provided guarantees; and

(iii) That is not an insurance company engaged predominately in the business of providing credit protection (such as a monoline bond insurer or re-insurer).

Eligible margin loan means:

(1) An extension of credit where:

(i) The extension of credit is collateralized exclusively by liquid and readily marketable debt or equity securities, or gold;

(ii) The collateral is marked-to-fair value daily, and the transaction is subject to daily margin maintenance requirements; and

(iii) The extension of credit is conducted under an agreement that provides the System institution the right to accelerate and terminate the extension of credit and to liquidate or set-off collateral promptly upon an event of default, including upon an event of receivership, insolvency, liquidation, conservatorship, or similar proceeding, of the counterparty, provided that, in any such case, any exercise of rights under the agreement will not be stayed or avoided under applicable law in the relevant jurisdictions, other than in receivership, conservatorship, resolution under the Federal Deposit Insurance Act, Title II of the Dodd-Frank Act, or under any similar insolvency law applicable to GSEs,[2] or laws of foreign jurisdictions that are substantially similar to the U.S. laws referenced in this paragraph (1)(iii) in order to facilitate the orderly resolution of the defaulting counterparty.

(2) In order to recognize an exposure as an eligible margin loan for purposes of this subpart, a System institution must comply with the requirements of § 628.3(b) with respect to that exposure.

Eligible servicer cash advance facility means a servicer cash advance facility in which:

(1) The servicer is entitled to full reimbursement of advances, except that a servicer may be obligated to make non-reimbursable advances for a particular underlying exposure if any such advance is contractually limited to an insignificant amount of the outstanding principal balance of that exposure;

(2) The servicer's right to reimbursement is senior in right of payment to all other claims on the cash flows from the underlying exposures of the securitization; and

(3) The servicer has no legal obligation to, and does not make advances to the securitization if the servicer concludes the advances are unlikely to be repaid.

Equity derivative contract means an equity-linked swap, purchased equity-linked option, forward equity-linked contract, or any other instrument linked to equities that gives rise to similar counterparty credit risks.

Equity exposure means:

(1) A security or instrument (whether voting or non-voting) that represents a direct or an indirect ownership interest in, and is a residual claim on, the assets and income of a company, unless:

(i) The issuing company is consolidated with the System institution under GAAP;

(ii) The System institution is required to deduct the ownership interest from tier 1 or tier 2 capital under this part;

(iii) The ownership interest incorporates a payment or other similar obligation on the part of the issuing company (such as an obligation to make periodic payments); or

(iv) The ownership interest is a securitization exposure;

(2) A security or instrument that is mandatorily convertible into a security or instrument described in paragraph (1) of this definition;

(3) An option or warrant that is exercisable for a security or instrument described in paragraph (1) of this definition; or

(4) Any other security or instrument (other than a securitization exposure) to the extent the return on the security or instrument is based on the performance of a security or instrument described in paragraph (1) of this definition.

ERISA means the Employee Retirement Income and Security Act of 1974 (29 U.S.C. 1001 *et seq.*).

Exchange rate derivative contract means a cross-currency interest rate swap, forward foreign-exchange contract, currency option purchased, or any other instrument linked to exchange rates that gives rise to similar counterparty credit risks.

Exposure means an amount at risk.

Exposure amount means:

(1) For the on-balance sheet component of an exposure (other than an available-for-sale or held-to-maturity security; an OTC derivative contract; a repo-style transaction or an eligible margin loan for which the System institution determines the exposure amount under § 628.37; a cleared transaction; or a securitization exposure), the System institution's carrying value of the exposure.

(2) For a security (that is not a securitization exposure, equity exposure, or preferred stock classified as an equity security under GAAP) classified as available-for-sale or held-to-maturity, the System institution's carrying value (including net accrued but unpaid interest and fees) for the exposure less any net unrealized gains on the exposure and plus any net unrealized losses on the exposure.

(3) For available-for-sale preferred stock classified as an equity security under GAAP, the System institution's carrying value of the exposure less any net unrealized gains on the exposure that are reflected in such carrying value but excluded from the System institution's regulatory capital components.

(4) For the off-balance sheet component of an exposure (other than an OTC derivative contract; a repo-style transaction or an eligible margin loan for which the System institution calculates the exposure amount under § 628.37; a cleared transaction; or a securitization exposure), the notional amount of the off-balance sheet component multiplied by the appropriate credit conversion factor (CCF) in § 628.33.

(5) For an exposure that is an OTC derivative contract, the exposure amount determined under § 628.34.

(6) For an exposure that is a cleared transaction, the exposure amount determined under § 628.35.

(7) For an exposure that is an eligible margin loan or repo-style transaction for which the bank calculates the exposure amount as provided in § 628.37, the exposure amount determined under § 628.37.

(8) For an exposure that is a securitization exposure, the exposure amount determined under § 628.42.

Farm Credit Act means the Farm Credit Act of 1971, as amended (12 U.S.C. 2001 *et seq.*).

Federal Deposit Insurance Act means the Federal Deposit Insurance Act (12 U.S.C. 1813).

Federal Deposit Insurance Corporation Improvement Act means the Federal Deposit Insurance Corporation Improvement Act of 1991 (12 U.S.C. 4401).

Financial collateral means collateral:

(1) In the form of:

(i) Cash on deposit at a depository institution or Federal Reserve Bank (including cash held for the System institution by a third-party custodian or trustee);

(ii) Gold bullion;

(iii) Long-term debt securities that are not resecuritization exposures and that are investment grade;

(iv) Short-term debt instruments that are not resecuritization exposures and that are investment grade;

(v) Equity securities that are publicly traded;

(vi) Convertible bonds that are publicly traded; or

(vii) Money market fund shares and other mutual fund shares if a price for the shares is publicly quoted daily; and

(2) In which the System institution has a perfected, first-priority security interest or, outside of the United States, the legal equivalent thereof (with the exception of cash on deposit at a depository institution or Federal Reserve Bank and notwithstanding the prior security interest of any custodial agent).

First-lien residential mortgage exposure means a residential mortgage exposure secured by a first lien.

Foreign bank means a foreign bank as defined in § 211.2 of the Federal Reserve Board's Regulation K (12 CFR 211.2) (other than a depository institution).

Forward agreement means a legally binding contractual obligation to purchase assets with certain drawdown at a specified future date, not including commitments to make residential mortgage loans or forward foreign exchange contracts.

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[2] This requirement is met where all transactions under the agreement are (i) executed under U.S. law and (ii) constitute "securities contracts" under section 555 of the Bankruptcy Code (11 U.S.C. 555), qualified financial contracts under section 11(e)(8) of the Federal Deposit Insurance Act, or netting contracts between or among financial institutions under sections 401–407 of the Federal Deposit Insurance Corporation Improvement Act of the Federal Reserve Board's Regulation EE (12 CFR part 231).

GAAP means generally accepted accounting principles as used in the United States.

Gain-on-sale means an increase in the equity capital of a System institution (as reported on the Call Report) resulting from a traditional securitization (other than an increase in equity capital resulting from the System institution's receipt of cash in connection with the securitization or reporting of a mortgage servicing asset on the Call Report).

General obligation means a bond or similar obligation that is backed by the full faith and credit of a public sector entity (PSE).

Government-sponsored enterprise (GSE) means an entity established or chartered by the U.S. Government to serve public purposes specified by the U.S. Congress but whose debt obligations are not explicitly guaranteed by the full faith and credit of the U.S. Government.

Guarantee means a financial guarantee, letter of credit, insurance, or other similar financial instrument (other than a credit derivative) that allows one party (beneficiary) to transfer the credit risk of one or more specific exposures (reference exposure) to another party (protection provider).

Home country means the country where an entity is incorporated, chartered, or similarly established.

Insurance company means an insurance company as defined in section 201 of the Dodd-Frank Act (12 U.S.C. 5381).

Insurance underwriting company means an insurance company as defined in section 201 of the Dodd-Frank Act (12 U.S.C. 5381) that engages in insurance underwriting activities.

Insured depository institution means an insured depository institution as defined in section 3 of the Federal Deposit Insurance Act.

Interest rate derivative contract means a single-currency interest rate swap, basis swap, forward rate agreement, purchased interest rate option, when-issued securities, or any other instrument linked to interest rates that gives rise to similar counterparty credit risks.

International Lending Supervision Act means the International Lending Supervision Act of 1983 (12 U.S.C. 3907).

Investment fund means a company:

(1) Where all or substantially all of the assets of the company are financial assets; and

(2) That has no material liabilities.

Investment grade means that the entity to which the System institution is exposed through a loan or security, or the reference entity with respect to a credit derivative, has adequate capacity to meet financial commitments for the projected life of the asset or exposure. Such an entity or reference entity has adequate capacity to meet financial commitments if the risk of its default is low and the full and timely repayment of principal and interest is expected.

Junior-lien residential mortgage exposure means a residential mortgage exposure that is not a first-lien residential mortgage exposure.

Member means a borrower or former borrower from a System institution that holds voting or nonvoting cooperative equities of the institution.

Money market fund means an investment fund that is subject to 17 CFR 270.2a–7 or any foreign equivalent thereof.

Mortgage servicing assets (MSAs) means the contractual rights owned by a System institution to service for a fee mortgage loans that are owned by others.

Multilateral development bank (MDB) means the International Bank for Reconstruction and Development, the Multilateral Investment Guarantee Agency, the International Finance Corporation, the Inter-American Development Bank, the Asian Development Bank, the African Development Bank, the European Bank for Reconstruction and Development, the European Investment Bank, the European Investment Fund, the Nordic Investment Bank, the Caribbean Development Bank, the Islamic Development Bank, the Council of Europe Development Bank, and any other multilateral lending institution or regional development bank in which the U.S. Government is a shareholder or contributing member or which the FCA determines poses comparable credit risk.

National Bank Act means the National Bank Act (12 U.S.C. 24).

Netting set means a group of transactions with a single counterparty that are subject to a qualifying master netting agreement or a qualifying cross-product master netting agreement. For purposes of calculating risk-based capital requirements using the internal models methodology in subpart E of this part, this term does not cover a transaction:

(1) That is not subject to such a master netting agreement; or

(2) Where the System institution has identified specific wrong-way risk.

Nonqualified allocated equities mean a patronage payment to a member-borrower in the form of stock or surplus that a System institution retains as equity for the benefit of the membership. A System institution does not deduct this patronage payment from its current taxable income according to the Internal Revenue Code sections 1382(b) and 1383. Nonqualified allocated equities also include allocated surplus in a tax-exempt institution or subsidiary. When a System institution revolves a nonqualified allocation, the System institution deducts the allocation from its taxable income, if any, and the borrower generally recognizes the tax liability, if any, as ordinary income. System institutions pay two types of nonqualified allocated equities through written notices of allocation to the borrowers:

(1) Those subject to revolvement; and

(2) Those not subject to revolvement. The second type for GAAP purposes is generally considered an equivalent of unallocated surplus and consolidated with unallocated surplus on externally prepared shareholder reports.

N^{th}-to-default credit derivative means a credit derivative that provides credit protection only for the nth-defaulting reference exposure in a group of reference exposures.

Operating entity means a company established to conduct business with clients with the intention of earning a profit in its own right and that generally produces goods or provides services beyond the business of investing, reinvesting, holding, or trading in financial assets. All System banks, associations, and service corporations, and all unincorporated business entities, are operating entities.

Original maturity with respect to an off-balance sheet commitment means the length of time between the date a commitment is issued and:

(1) For a commitment that is not subject to extension or renewal, the stated expiration date of the commitment; or

(2) For a commitment that is subject to extension or renewal, the earliest date on which the System institution can, at its option, unconditionally cancel the commitment.

Originating System institution, with respect to a securitization, means a System institution that:

(1) Directly or indirectly originated the underlying exposures included in the securitization; or

(2) [Reserved]

Other financing institution (OFI) means any entity referred to in section 1.7(b)(1)(B) of the Farm Credit Act.

Over-the-counter (OTC) derivative contract means a derivative contract that is not a cleared transaction.

Participation certificate means borrower stock held by a borrower or customer of a System institution that does not have voting rights.

Patronage payment means a cash declaration or equity allocation to member-borrowers that pursuant to Internal Revenue Code section 1381(a) is based on a System institution's net income and allocated to borrowers based on business conducted with the institution. Patronage payments may be paid as cash, allocated equity (stock or surplus), or a combination of cash and allocated equity.

Performance standby letter of credit (or performance bond) means an irrevocable obligation of a System institution to pay a third-party beneficiary when a customer (account party) fails to perform on any contractual nonfinancial or commercial obligation. To the extent permitted by law or regulation, performance standby letters of credit include arrangements backing, among other things; subcontractors' and suppliers' performance, labor; and materials contracts, and construction bids.

Protection amount (P) means, with respect to an exposure hedged by an eligible guarantee or eligible credit derivative, the effective notional amount of the guarantee or credit derivative, reduced to reflect any currency mismatch, maturity mismatch, or lack of restructuring coverage (as provided in § 628.36).

Publicly traded means traded on:

(1) Any exchange registered with the Securities and Exchange Commission (SEC) as a national securities exchange under section 6 of the Securities Exchange Act; or

(2) Any non-U.S.-based securities exchange that:

(i) Is registered with, or approved by, a national securities regulatory authority; and

(ii) Provides a liquid, two-way market for the instrument in question.

Public sector entity (PSE) means a state, local authority, or other governmental subdivision below the sovereign level.

Qualified allocated equities means patronage allocated to a member-borrower, in the form of stock or surplus, that a System institution retains as equity for the benefit of the membership. A System institution can deduct this patronage from its current taxable income provided that the borrower has agreed to include the patronage in its taxable income. A System institution must pay at least 20 percent of a qualified patronage payment in cash to borrowers. A System institution must provide the borrowers with a qualified written notice of allocation when they allocate qualified patronage payments pursuant to Internal Revenue Code section 1381(b) and 1388(c). A System institution revolves qualified allocated equities according to a board-approved plan.

Qualifying central counterparty (QCCP) means a central counterparty that:

(1)(i) Is a designated financial market utility (FMU), as defined in section 803 of the Dodd-Frank Act;

(ii) If not located in the United States, is regulated and supervised in a manner equivalent to a designated FMU; or

(iii) Meets the following standards:

(A) The central counterparty requires all parties to contracts cleared by the counterparty to be fully collateralized on a daily basis;

(B) The System institution demonstrates to the satisfaction of the FCA that the central counterparty:

(*1*) Is in sound financial condition;

(*2*) Is subject to supervision by the Board, the CFTC, or the Securities Exchange Commission (SEC), or, if the central counterparty is not located in the United States, is subject to effective oversight by a national supervisory authority in its home country; and

(*3*) Meets or exceeds the risk-management standards for central counterparties set forth in regulations established by the Board, the CFTC, or the SEC under title VII or title VIII of the Dodd-Frank Act; or if the central counterparty is not located in the United States, meets or exceeds similar risk-management standards established under the law of its home country that are consistent with international standards for central counterparty risk management as established by the relevant standard setting body of the Bank of International Settlements; and

(2)(i) Provides the System institution with the central counterparty's hypothetical capital requirement or the information necessary to calculate such hypothetical capital requirement, and other information the System institution is required to obtain under § 628.35(d)(3);

(ii) Makes available to the FCA and the CCP's regulator the information described in paragraph (2)(i) of this definition; and

(iii) Has not otherwise been determined by the FCA to not be a QCCP due to its financial condition, risk profile, failure to meet supervisory risk management standards, or other weaknesses or supervisory concerns that are inconsistent with the risk weight assigned to qualifying central counterparties under § 628.35.

(3) A QCCP that fails to meet the requirements of a QCCP in the future may still be treated as a QCCP under the conditions specified in § 628.3(f).

Qualifying master netting agreement means a written, legally enforceable agreement provided that:

(1) The agreement creates a single legal obligation for all individual transactions covered by the agreement upon an event of default following any stay permitted by paragraph (2) of this definition, including upon an event of receivership, conservatorship, insolvency, liquidation, or similar proceeding, of the counterparty;

(2) The agreement provides the System institution the right to accelerate, terminate, and close-out on a net basis all transactions under the agreement and to liquidate or set-off collateral promptly upon an event of default, including upon an event of receivership, conservatorship, insolvency, liquidation, or similar proceeding, of the counterparty, provided that, in any such case, any exercise of rights under the agreement will not be stayed or avoided under applicable law in the relevant jurisdictions, other than:

(i) In receivership, conservatorship, or resolution under the Federal Deposit Insurance Act, title II of the Dodd-Frank Act, or under any similar insolvency law applicable to GSEs, or laws of foreign jurisdictions that are substantially similar to the U.S. laws referenced in this paragraph (2)(i) in order to facilitate the orderly resolution of the defaulting counterparty; or

(ii) Where the agreement is subject by its terms to, or incorporates, any of the laws reference in paragraph (2)(i) of this definition;

(3) The agreement does not contain a walkaway clause (that is, a provision that permits a non-defaulting counterparty to make a lower payment than it otherwise would make under the agreement, or no payment at all, to a defaulter or the estate of a defaulter, even if the defaulter or the estate of the defaulter is a net creditor under the agreement); and

(4) In order to recognize an agreement as a qualifying master netting agreement for purposes of this subpart, a System institution must comply with the requirements of § 628.3(d) with respect to that agreement.

Repo-style transaction means a repurchase or reverse repurchase transaction, or a securities borrowing or securities lending transaction, including a transaction in which the System institution acts as agent for a customer and indemnifies the customer against loss, provided that:

(1) The transaction is based solely on liquid and readily marketable securities, cash, or gold;

(2) The transaction is marked-to-fair value daily and subject to daily margin maintenance requirements;

(3)(i) The transaction is a "securities contract" or "repurchase agreement" under section 555 or 559, respectively, of the Bankruptcy Code (11 U.S.C. 555 or 559) or a qualified financial contract under section 11(e)(8) of the Federal Deposit Insurance Act; or

(ii) If the transaction does not meet the criteria set forth in paragraph (3)(i) of this definition, then either:

(A) The transaction is executed under an agreement that provides the System institution the right to accelerate, terminate, and close-out the transaction on a net basis and to liquidate or set-off collateral promptly upon an event of default, including upon an event of receivership, insolvency, liquidation, or similar proceeding, of the counterparty, provided that, in any such case, any exercise of rights under the agreement will not be stayed or avoided under applicable law in the relevant jurisdictions, other than in receivership, conservatorship, or resolution under the Federal Deposit Insurance Act, title II of the Dodd-Frank Act, or under any similar insolvency law applicable to GSEs, or laws of foreign jurisdictions that are substantially similar to the U.S. laws referenced in this paragraph (3)(ii)(A) in order to facilitate the orderly resolution of the defaulting counterparty; or

(B) The transaction is:

(*1*) Either overnight or unconditionally cancelable at any time by the System institution; and

(*2*) Executed under an agreement that provides the System institution the right to accelerate, terminate, and close-out the transaction on a net basis and to liquidate or set-off collateral promptly upon an event of counterparty default; and

(*3*) [Reserved]

(*4*) In order to recognize an exposure as a repo-style transaction for purposes of this subpart, a System institution must comply with the requirements of § 628.3(e) of this part with respect to that exposure.

Resecuritization means a securitization which has more than one underlying exposure and in which one or more of the underlying exposures is a securitization exposure.

Resecuritization exposure means:

(1) An on- or off-balance sheet exposure to a resecuritization; or

(2) An exposure that directly or indirectly references a resecuritization exposure.

Residential mortgage exposure means an exposure (other than a securitization exposure or equity exposure) that is:

(1) An exposure that is primarily secured by a first or subsequent lien on one-to-four family residential property, provided that the dwelling (including attached components such as garages, porches, and decks) represents at least 50 percent of the total appraised value of the collateral secured by the first or subsequent lien; or

(2) [Reserved]

Revenue obligation means a bond or similar obligation that is an obligation of a PSE, but which the PSE is committed to repay with revenues from the specific project financed rather than general tax funds.

Savings and loan holding company means a savings and loan holding company as defined in section 10 of the Home Owners' Loan Act (12 U.S.C. 1467a).

Securities and Exchange Commission (SEC) means the U.S. Securities and Exchange Commission.

Securities Exchange Act means the Securities Exchange Act of 1934 (15 U.S.C. 78).

Securitization exposure means:

(1) An on-balance sheet or off-balance sheet credit exposure (including credit-enhancing representations and warranties) that arises from a traditional securitization or synthetic securitization (including a resecuritization); or

(2) An exposure that directly or indirectly references a securitization exposure described in paragraph (1) of this definition.

Securitization special purpose entity (securitization SPE) means a corporation, trust, or other entity organized for the specific purpose of holding underlying exposures of a securitization, the activities of which are limited to those appropriate to accomplish this purpose, and the structure of which is intended to isolate the underlying exposures held by the entity from the credit risk of the seller of the underlying exposures to the entity.

Servicer cash advance facility means a facility under which the servicer of the underlying exposures of a securitization may advance cash to ensure an uninterrupted flow of payments to investors in the securitization, including advances made to cover foreclosure costs or other expenses to facilitate the timely collection of the underlying exposures.

Small Business Act means the Small Business Act (15 U.S.C. 632).

Small Business Investment Act means the Small Business Investment Act of 1958 (15 U.S.C. 682).

Sovereign means a central government (including the U.S. Government) or an agency, department, ministry, or central bank of a central government.

Sovereign default means noncompliance by a sovereign with its external debt service obligations or the inability or unwillingness of a sovereign government to service an existing loan according to its original terms, as evidenced by failure to pay principal and interest timely and fully, arrearages, or restructuring.

Sovereign exposure means:

(1) A direct exposure to a sovereign; or

(2) An exposure directly and unconditionally backed by the full faith and credit of a sovereign.

Standardized total risk-weighted assets means:

(1) The sum of:

(i) Total risk-weighted assets for general credit risk as calculated under § 628.31;

(ii) Total risk-weighted assets for cleared transactions as calculated under § 628.35;

(iii) Total risk-weighted assets for unsettled transactions as calculated under § 628.38;

(iv) Total risk-weighted assets for securitization exposures as calculated under § 628.42;

(v) Total risk-weighted assets for equity exposures as calculated under §§ 628.52 and 628.53; minus

(vi) [Reserved]

(2) Any amount of the System institution's allowance for loan losses that is not included in tier 2 capital.

Subsidiary means, with respect to a company, a company controlled by that company.

Synthetic exposure means an exposure whose value is linked to the value of an investment in the System institution's own capital instrument.

Synthetic securitization means a transaction in which:

(1) All or a portion of the credit risk of one or more underlying exposures is retained or transferred to one or more third parties through the use of one or more credit derivatives or guarantees (other than a guarantee that transfers only the credit risk of an individual retail exposure);

(2) The credit risk associated with the underlying exposures has been separated into at least two tranches reflecting different levels of seniority;

(3) Performance of the securitization exposures depends upon the performance of the underlying exposures; and

(4) All or substantially all of the underlying exposures are financial exposures (such as loans, commitments, credit derivatives, guarantees, receivables, asset-backed securities, mortgage-backed securities, other debt securities, or equity securities).

System bank means a Farm Credit Bank, an agricultural credit bank, and a bank for cooperatives.

System institution means a System bank, an association of the Farm Credit System, Farm Credit Leasing Services Corporation, and their successors, and any other institution chartered by the FCA that the FCA determines should be considered a System institution for the purposes of this part.

Tier 1 capital means the sum of common equity tier 1 capital and additional tier 1 capital.

Tier 2 capital is defined in § 628.20(d).

Total capital means the sum of tier 1 capital and tier 2 capital.

Traditional securitization means a transaction in which:

(1) All or a portion of the credit risk of one or more underlying exposures is transferred to one or more third parties other than through the use of credit derivatives or guarantees;

(2) The credit risk associated with the underlying exposures has been separated into at least two tranches reflecting different levels of seniority;

(3) Performance of the securitization exposures depends upon the performance of the underlying exposures;

(4) All or substantially all of the underlying exposures are financial exposures (such as loans, commitments, credit derivatives, guarantees, receivables, asset-backed securities, mortgage-backed securities, other debt securities, or equity securities);

(5) The underlying exposures are not owned by an operating entity;

(6) The underlying exposures are not owned by a rural business investment company described in 7 U.S.C. 2009cc *et seq.;*

(7) [Reserved]

(8) The FCA may determine that a transaction in which the underlying exposures are owned by an investment firm that exercises substantially unfettered control over the size and composition of its assets, liabilities, and off-balance sheet exposures is not a traditional securitization based on the transaction's leverage, risk profile, or economic substance;

(9) The FCA may deem a transaction that meets the definition of a traditional securitization, notwithstanding paragraph (5), (6), or (7) of this definition, to be a traditional securitization based on the transaction's leverage, risk profile, or economic substance; and

(10) The transaction is not:

(i) An investment fund;

(ii) A collective investment fund (as defined in [12 CFR 9.18 (national bank) and 12 CFR 151.40 (Federal saving association) (OCC); 12 CFR 208.34 (Board)];

(iii) An employee benefit plan (as defined in paragraphs (3) and (32) of section 3 of ERISA), a "governmental plan" (as defined in 29 U.S.C. 1002(32)) that complies with the tax deferral qualification requirements provided in the Internal Revenue Code, or any similar employee benefit plan established under the laws of a foreign jurisdiction;

(iv) A synthetic exposure to the capital of a System institution to the extent deducted from capital under § 628.22; or

(v) Registered with the SEC under the Investment Company Act of 1940 (15 U.S.C. 80a–1) or foreign equivalents thereof.

Tranche means all securitization exposures associated with a securitization that have the same seniority level.

Two-way market means a market where there are independent bona fide offers to buy and sell so that a price reasonably related to the last sales price or current bona fide competitive bid and offer quotations can be determined within 1 day and settled at that price within a relatively short timeframe conforming to trade custom.

Unallocated retained earnings (URE) means accumulated net income that a System institution has not allocated to a member-borrower.

Unallocated retained earnings (URE) equivalents means nonqualified allocated equities, other than equities allocated to other System institutions, and paid-in capital resulting from a merger of System institutions or from a repurchase of third-party capital that a System institution:

(1) Designates as URE equivalents at the time of allocation (or on or before March 31, 2017, if allocated prior to January 1, 2017) and undertakes in its capitalization bylaws or a currently effective board of directors resolution not to change the designation without prior FCA approval; and

(2) Undertakes, in its capitalization bylaws or a currently effective board of directors resolution, not to exercise its discretion to revolve except upon dissolution or liquidation and not to offset against a loan in default except as required under final order of a court of competent jurisdiction or if required under § 615.5290 of this chapter in connection with a restructuring under part 617 of this chapter.

Unconditionally cancelable means, with respect to a commitment that a System institution may, at any time, with or without cause, refuse to extend credit under the commitment (to the extent permitted under applicable law).

Underlying exposures means one or more exposures that have been securitized in a securitization transaction.

U.S. Government agency means an instrumentality of the U.S. Government whose obligations are fully guaranteed as to the timely payment of principal and interest by the full faith and credit of the U.S. Government.

§ 628.3 Operational requirements for certain exposures.

For purposes of calculating risk-weighted assets under subpart D of this part:

(a) *Cleared transaction.* In order to recognize certain exposures as cleared transactions pursuant to paragraph (1)(ii), (iii), or (iv) of the definition of "cleared transaction" in § 628.2, the exposures must meet all of the requirements set forth in this paragraph (a).

(1) The offsetting transaction must be identified by the CCP as a transaction for the clearing member client.

(2) The collateral supporting the transaction must be held in a manner that prevents the System institution from facing any loss due to an event of default, including from a liquidation, receivership, insolvency, or similar proceeding of either the clearing member or the clearing member's other clients. Omnibus accounts established under 17 CFR parts 190 and 300 satisfy the requirements of this paragraph (a).

(3) The System institution must conduct sufficient legal review to conclude with a well-founded basis (and maintain sufficient written documentation of that legal review) that in the event of a legal challenge (including one resulting from a default or receivership, insolvency, liquidation, or similar proceeding) the relevant court and administrative authorities would find the arrangements of paragraph (a)(2) of this section to be legal, valid, binding and enforceable under the law of the relevant jurisdictions.

(4) The offsetting transaction with a clearing member must be transferable under the transaction documents and applicable laws in the relevant jurisdiction(s) to another clearing member should the clearing member default, become insolvent, or enter

receivership, insolvency, liquidation, or similar proceedings.

(b) *Eligible margin loan.* In order to recognize an exposure as an eligible margin loan as defined in § 628.2, a System institution must conduct sufficient legal review to conclude with a well-founded basis (and maintain sufficient written documentation of that legal review) that the agreement underlying the exposure:

(1) Meets the requirements of paragraph (1)(iii) of the definition of "eligible margin loan" in § 628.2; and

(2) Is legal, valid, binding, and enforceable under applicable law in the relevant jurisdictions.

(c) [Reserved]

(d) *Qualifying master netting agreement.* In order to recognize an agreement as a qualifying master netting agreement as defined in § 628.2, a System institution must:

(1) Conduct sufficient legal review to conclude with a well-founded basis (and maintain sufficient written documentation of that legal review) that:

(i) The agreement meets the requirements of paragraph (2) of the definition of "qualifying master netting agreement" in § 628.2; and

(ii) In the event of a legal challenge (including one resulting from default or from receivership, insolvency, liquidation, or similar proceeding) the relevant court and administrative authorities would find the agreement to be legal, valid, binding, and enforceable under the law of the relevant jurisdictions; and

(2) Establish and maintain written procedures to monitor possible changes in relevant law and to ensure that the agreement continues to satisfy the requirements of the definition of "qualifying master netting agreement" in § 628.2.

(e) *Repo-style transaction.* In order to recognize an exposure as a repo-style transaction as defined in § 628.2, a System institution must conduct sufficient legal review to conclude with a well-founded basis (and maintain sufficient written documentation of that legal review) that the agreement underlying the exposure:

(1) Meets the requirements of paragraph (3) of the definition of "repo-style transaction" in § 628.2, and

(2) Is legal, valid, binding, and enforceable under applicable law in the relevant jurisdictions.

(f) *Failure of a QCCP to satisfy the rule's requirements.* If a System institution determines that a CCP ceases to be a QCCP due to the failure of the CCP to satisfy one or more of the requirements set forth in paragraph (2)(i) through (iii) of the definition of a "QCCP" in § 628.2, the System institution may continue to treat the CCP as a QCCP for up to 3 months following the determination. If the CCP fails to remedy the relevant deficiency within 3 months after the initial determination, or the CCP fails to satisfy the requirements set forth in paragraph (2)(i) through (iii) of the definition of a QCCP continuously for a 3-month period after remedying the relevant deficiency, a System institution may not treat the CCP as a QCCP for the purposes of this part until after the System institution has determined that the CCP has satisfied the requirements in paragraph (2)(i) through (iii) of the definition of a QCCP for 3 continuous months.

§§ 628.4–628.9 [Reserved]

Subpart B—Capital Ratio Requirements and Buffers

§ 628.10 Minimum capital requirements.

(a) *Computation of regulatory capital ratios.* A System institution's regulatory capital ratios are determined on the basis of the financial statements of the institution prepared in accordance with GAAP using average daily balances for the most recent 3 months.

(b) *Minimum capital requirements.* A System institution must maintain the following minimum capital ratios:

(1) A common equity tier 1 (CET1) capital ratio of 4.5 percent.

(2) A tier 1 capital ratio of 6 percent.

(3) A total capital ratio of 8 percent.

(4) A tier 1 leverage ratio of 4 percent, of which at least 1.5 percent must be composed of URE and URE equivalents.

(5) [Reserved]

(6) A permanent capital ratio of 7 percent.

(c) *Capital ratio calculations.* A System institution's regulatory capital ratios are as follows:

(1) *CET1 capital ratio.* A System institution's CET1 capital ratio is the ratio of the System institution's CET1 capital to total risk-weighted assets;

(2) *Tier 1 capital ratio.* A System institution's tier 1 capital ratio is the ratio of the System institution's tier 1 capital to total risk-weighted assets;

(3) *Total capital ratio.* A System institution's total capital ratio is the ratio of the System institution's total (tier 1 and tier 2) capital to total risk-weighted assets; and

(4) *Tier 1 leverage ratio.* A System institution's leverage ratio is the ratio of the institution's tier 1 capital to the institution's average total consolidated assets as reported on the institution's Call Report minus amounts deducted from tier 1 capital under §§ 628.22(a) and (c) and 628.23.

(5) *Permanent capital ratio.* A System institution's permanent capital ratio is the ratio of the institution's permanent capital to its total risk-adjusted asset base as reported on the institution's Call Report, calculated in accordance with the regulations in part 615, subpart H, of this chapter.

(d) [Reserved]

(e) *Capital adequacy.* (1) Notwithstanding the minimum requirements in this part, a System institution must maintain capital commensurate with the level and nature of all risks to which the System institution is exposed. FCA may evaluate a System institution's capital adequacy and require the institution to maintain higher minimum regulatory capital ratios using the factors listed in § 615.5350 of this chapter.

(2) A System institution must have a process for assessing its overall capital adequacy in relation to its risk profile and a comprehensive strategy for maintaining an appropriate level of capital under § 615.5200 of this chapter.

§ 628.11 Capital buffer amounts.

(a) *Capital conservation buffer and leverage buffer*—(1) *Composition of the capital conservation buffer and leverage buffer.* (i) The capital conservation buffer for the CET1 capital ratio, tier 1 capital ratio, and total capital ratio is composed solely of CET1 capital.

(ii) The leverage buffer for the tier 1 leverage ratio is composed solely of tier 1 capital.

(2) *Definitions.* For purposes of this section, the following definitions apply:

(i) *Eligible retained income.* The eligible retained income of a System institution is the System institution's net income for the 4 calendar quarters preceding the current calendar quarter, based on the System institution's quarterly Call Reports, net of any capital distributions and associated tax effects not already reflected in net income.

(ii) *Maximum payout ratio.* The maximum payout ratio is the percentage of eligible retained income that a System institution can pay out in the form of capital distributions and discretionary bonus payments during the current calendar quarter. The maximum payout ratio is based on the System institution's capital conservation buffer, calculated as of the last day of the previous calendar quarter, as set forth in Table 1 to § 628.11.

(iii) *Maximum payout amount.* A System institution's maximum payout amount for the current calendar quarter is equal to the System institution's eligible retained income, multiplied by the applicable maximum payout ratio, as set forth in Table 1 to § 628.11.

(iv) [Reserved]

(v) *Maximum leverage payout ratio.* The maximum leverage payout ratio is the percentage of eligible retained income that a System institution can pay out in the form of capital distributions and discretionary bonus payments during the current quarter. The maximum leverage payout ratio is based on the System institution's leverage buffer, calculated as of the last day of the previous quarter, as set forth in Table 2 to § 628.11.

(vi) *Maximum leverage payout amount.* A System institution's maximum leverage payout amount for the current calendar quarter is equal to the System institution's eligible retained income, multiplied by the applicable maximum leverage payout ratio, as set forth in Table 2 of § 628.11.

(vii) *Capital distribution* means:

(A) A reduction of tier 1 capital through the repurchase, redemption, or revolvement of a tier 1 capital instrument or by other means, except when a System institution, within the same quarter when the repurchase is announced, fully replaces a tier 1 capital instrument it has repurchased, redeemed, or revolved by issuing a purchased capital instrument that meets the eligibility criteria for:

(*1*) A CET1 capital instrument if the instrument being repurchased, redeemed, or revolved was part of the System institution's CET1 capital; or

(*2*) A CET1 or AT1 capital instrument if the instrument being repurchased, redeemed, or revolved was part of the System institution's tier 1 capital;

(B) A reduction of tier 2 capital through the repurchase, redemption prior to maturity, or revolvement of a tier 2 capital instrument or by other means, except when a System institution, within the same quarter when the repurchase, redemption, or revolvement is announced, fully replaces a tier 2 capital instrument it has repurchased, redeemed, or revolved by issuing a purchased capital instrument that meets the eligibility criteria for a tier 1 or tier 2 capital instrument;

(C) A dividend declaration or payment on any tier 1 capital instrument;

(D) A dividend declaration or interest payment on any capital instrument other than a tier 1 capital instrument if the System institution has full discretion to permanently or temporarily suspend such payments without triggering an event of default;

(E) A cash patronage declaration or payment;

(F) A patronage declaration in the form of allocated equities that did not qualify as tier 1 or tier 2 capital; or

(G) Any similar transaction that the FCA determines to be in substance a distribution of capital.

(viii) *Discretionary bonus payment* means a payment made to a senior officer of a System institution, where:

(A) The System institution retains discretion as to whether to make, and the amount of, the payment until the payment is awarded to the senior officer;

(B) The amount paid is determined by the System institution without prior promise to, or agreement with, the senior officer; and

(C) The senior officer has no contractual right, whether express or implied, to the bonus payment.

(ix) *Senior officer* means the Chief Executive Officer, the Chief Operations Officer, the Chief Financial Officer, the Chief Credit Officer, and the General Counsel, or persons in similar positions; and any other person responsible for a major policy-making function.

(3) *Calculation of capital conservation buffer and leverage buffer.* (i) A System institution's capital conservation buffer is equal to the lowest of paragraphs (a)(3)(i)(A), (B), and (C) of this section, and the leverage buffer is equal to paragraph (a)(3)(i)(D) of this section, calculated as of the last day of the previous calendar quarter based on the System institution's most recent Call Report:

(A) The System institution's CET1 capital ratio minus the System institution's minimum CET1 capital ratio requirement under § 628.10;

(B) The System institution's tier 1 capital ratio minus the System institution's minimum tier 1 capital ratio requirement under § 628.10;

(C) The System institution's total capital ratio minus the System institution's minimum total capital ratio requirement under § 628.10; and

(D) The System institution's tier 1 leverage ratio minus the System institution's minimum tier 1 leverage ratio requirement under § 628.10.

(ii) Notwithstanding paragraphs (a)(3)(i)(A) through (D) of this section, if the System institution's CET1 capital ratio, tier 1 capital ratio, total capital ratio or tier 1 leverage ratio is less than or equal to the System institution's minimum CET1 capital ratio, tier 1 capital ratio, total capital ratio or tier 1 leverage ratio requirement under § 628.10, respectively, the System institution's capital conservation buffer or leverage buffer is zero.

(4) *Limits on capital distributions and discretionary bonus payments.* (i) A System institution must not make capital distributions or discretionary bonus payments or create an obligation to make such capital distributions or payments during the current calendar quarter that, in the aggregate, exceed the maximum payout amount or, as applicable, the maximum leverage payout amount.

(ii) A System institution that has a capital conservation buffer that is greater than 2.5 percent and a leverage buffer that is greater than 1.0 percent is not subject to a maximum payout amount or maximum leverage payout amount under this section.

(iii) *Negative eligible retained income.* Except as provided in paragraph (a)(4)(iv) of this section, a System institution may not make capital distributions or discretionary bonus payments during the current calendar quarter if the System institution's:

(A) Eligible retained income is negative; and

(B) Capital conservation buffer was less than 2.5 percent, or the leverage buffer was less than 1.0 percent, as of the end of the previous calendar quarter.

(iv) *Prior approval.* Notwithstanding the limitations in paragraphs (a)(4)(i) through (iii) of this section, FCA may permit a System institution to make a capital distribution or discretionary bonus payment upon a request of the System institution, if FCA determines that the capital distribution or discretionary bonus payment would not be contrary to the purposes of this section, or to the safety and soundness of the System institution. In making such a determination, FCA will consider the nature and extent of the request and the particular circumstances giving rise to the request.

TABLE 1 TO § 628.11—CALCULATION OF MAXIMUM PAYOUT AMOUNT

Capital conservation buffer	Maximum payout ratio (as a percentage of eligible retained income)
>2.500 percent	No limitation.
≤2.500 percent, and >1.875 percent.	60 percent.
≤1.875 percent, and >1.250 percent.	40 percent.
≤1.250 percent, and >0.625 percent.	20 percent.
≤0.625 percent	0 percent.

TABLE 2 TO § 628.11—CALCULATION OF MAXIMUM LEVERAGE PAYOUT AMOUNT

Leverage buffer	Maximum leverage payout ratio (as a percentage of eligible retained income)
>1.00 percent	No limitation.
≤1.00 percent, and >0.75 percent.	60 percent.
≤0.75 percent, and >0.50 percent.	40 percent.
≤0.50 percent, and >0.25 percent.	20 percent.
≤0.25 percent	0 percent.

(v) *Other limitations on* capital distributions. Additional limitations on capital distributions may apply to a System institution under subpart C of this part and under part 615, subparts L and M, of this chapter.

(vi) A System institution is subject to the lower of the maximum payout amount as determined under paragraph (a)(2)(iii) of this section and the maximum leverage payout amount as determined under paragraph (a)(2)(vi) of this section.

(b) [Reserved]

§§ 628.12–628.19 [Reserved]

Subpart C—Definition of Capital

§ 628.20 Capital components and eligibility criteria for tier 1 and tier 2 capital instruments.

(a) *Regulatory capital components.* A System institution's regulatory capital components are:

(1) CET1 capital;

(2) AT1 capital; and

(3) Tier 2 capital.

(b) *CET1 capital.* CET1 capital is the sum of the CET1 capital elements in paragraph (b) of this section, minus regulatory adjustments and deductions in § 628.22. The CET1 capital elements are:

(1) Any common cooperative equity instrument issued by a System institution that meets all of the following criteria:

(i) The instrument is issued directly by the System institution and represents a claim subordinated to general creditors, subordinated debt holders, and preferred stock holders in a receivership, insolvency, liquidation, or similar proceeding of the System institution;

(ii) The holder of the instrument is entitled to a claim on the residual assets of the System institution, the claim will be paid only after all creditors, subordinated debt holders, and preferred stock claims have been satisfied in a receivership, insolvency, liquidation, or similar proceeding;

(iii) The instrument has no maturity date, can be redeemed only at the discretion of the System institution and with the prior approval of FCA, and does not contain any term or feature that creates an incentive to redeem;

(iv) The System institution did not create, through any action or communication, an expectation that it will buy back, cancel, redeem, or revolve the instrument, and the instrument does not include any term or feature that might give rise to such an expectation, except that the establishment of a revolvement period of 7 years or more, or the practice of redeeming or revolving the instrument no less than 7 years after issuance or allocation, will not be considered to create such an expectation;

(v) Any cash dividend payments on the instrument are paid out of the System institution's net income or unallocated retained earnings, and are not subject to a limit imposed by the contractual terms governing the instrument;

(vi) The System institution has full discretion at all times to refrain from paying any dividends without triggering an event of default, a requirement to make a payment-in-kind, or an imposition of any other restrictions on the System institution;

(vii) Dividend payments and other distributions related to the instrument may be paid only after all legal and contractual obligations of the System institution have been satisfied, including payments due on more senior claims;

(viii) The holders of the instrument bear losses as they occur before any losses are borne by holders of preferred stock claims on the System institution and holders of any other claims with priority over common cooperative equity instruments in a receivership, insolvency, liquidation, or similar proceeding;

(ix) The instrument is classified as equity under GAAP;

(x) The System institution, or an entity that the System institution controls, did not purchase or directly or indirectly fund the purchase of the instrument, except that where there is an obligation for a member of the institution to hold an instrument in order to receive a loan or service from the System institution, an amount of that loan equal to the minimum borrower stock requirement under section 4.3A of the Act will not be considered as a direct or indirect funding where:

(A) The purpose of the loan is not the purchase of capital instruments of the System institution providing the loan; and

(B) The purchase or acquisition of one or more member equities of the institution is necessary in order for the beneficiary of the loan to become a member of the System institution;

(xi) The instrument is not secured, not covered by a guarantee of the System institution, and is not subject to any other arrangement that legally or economically enhances the seniority of the instrument;

(xii) The instrument is issued in accordance with applicable laws and regulations and with the institution's capitalization bylaws;

(xiii) The instrument is reported on the System institution's regulatory financial statements separately from other capital instruments; and

(xiv) The System institution's capitalization bylaws, or a resolution adopted by its board of directors under § 615.5200(d) of this chapter and re-affirmed by the board on an annual basis, provides that the institution:

(A) Establishes a minimum redemption or revolvement period of 7 years for equities included in CET1; and

(B) Shall not redeem, revolve, cancel, or remove any equities included in CET1 without prior approval of the FCA under § 628.20(f), except that the minimum statutory borrower stock described in paragraph (b)(1)(x) of this section may be redeemed without a minimum period outstanding after issuance and without the prior approval of the FCA.

(2) Unallocated retained earnings.

(3) Paid-in capital resulting from a merger of System institutions or repurchase of third-party capital.

(4) [Reserved]

(5) [Reserved]

(c) *AT1 capital.* AT1 capital is the sum of additional tier 1 capital elements and related surplus, minus the regulatory adjustments and deductions in §§ 628.22 and 628.23. AT1 capital elements are:

(1) Instruments and related surplus, other than common cooperative equities, that meet the following criteria:

(i) The instrument is issued and paid-in;

(ii) The instrument is subordinated to general creditors and subordinated debt holders of the System institution in a receivership, insolvency, liquidation, or similar proceeding;

(iii) The instrument is not secured, not covered by a guarantee of the System institution and not subject to any other arrangement that legally or economically enhances the seniority of the instrument;

(iv) The instrument has no maturity date and does not contain a dividend step-up or any other term or feature that creates an incentive to redeem;

(v) If callable by its terms, the instrument may be called by the System institution only after a minimum of 5 years following issuance, except that the terms of the instrument may allow it to be called earlier than 5 years upon the occurrence of a regulatory event that precludes the instrument from being included in AT1 capital, or a tax event. In addition:

(A) The System institution must receive prior approval from FCA to exercise a call option on the instrument.

(B) The System institution does not create at issuance of the instrument, through any action or communication, an expectation that the call option will be exercised.

(C) Prior to exercising the call option, or immediately thereafter, the System institution must either replace the instrument to be called with an equal amount of instruments that meet the criteria under paragraph (b) of this section or this paragraph (c),[3] or demonstrate to the satisfaction of FCA that following redemption, the System institution will continue to hold capital commensurate with its risk;

(vi) Redemption or repurchase of the instrument requires prior approval from FCA;

(vii) The System institution has full discretion at all times to cancel dividends or other distributions on the instrument without triggering an event of default, a requirement to make a payment-in-kind, or an imposition of other restrictions on the System institution except in relation to any distributions to holders of common cooperative equity instruments or other instruments that are pari passu with the instrument;

(viii) Any distributions on the instrument are paid out of the System institution's net income, unallocated retained earnings, or surplus related to other AT1 capital instruments;

(ix) The instrument does not have a credit-sensitive feature, such as a dividend rate that is reset periodically based in whole or in part on the System institution's credit quality, but may have a dividend rate that is adjusted periodically independent of the System institution's credit quality, in relation to general market interest rates or similar adjustments;

(x) The paid-in amount is classified as equity under GAAP;

(xi) The System institution did not purchase or directly or indirectly fund the purchase of the instrument;

(xii) The instrument does not have any features that would limit or discourage additional issuance of capital by the System institution, such as provisions that require the System institution to compensate holders of the instrument if a new instrument is issued at a lower price during a specified timeframe; and

(xiii) [Reserved]

(xiv) The System institution's capitalization bylaws, or a resolution adopted by its board of directors under § 615.5200(d) of this chapter and re-affirmed by the board on an annual basis, provides that the institution:

(A) Establishes a minimum redemption or no-call period of 5 years for equities included in additional tier 1; and

(B) Shall not redeem, revolve, cancel, or remove any equities included in additional tier 1 capital without prior approval of the FCA under § 628.20(f).

(2) [Reserved]

(3) [Reserved]

(4) Notwithstanding the criteria for AT1 capital instruments referenced in paragraph (c)(1) of this section:

(i) [Reserved]

(ii) An instrument with terms that provide that the instrument may be called earlier than 5 years upon the occurrence of a rating agency event does not violate the criterion in paragraph (c)(1)(v) of this section provided that the instrument was issued and included in a System institution's core surplus capital prior to January 1, 2017, and that such instrument satisfies all other criteria under this § 628.20(c).

(d) *Tier 2 Capital.* Tier 2 capital is the sum of tier 2 capital elements and any related surplus minus regulatory adjustments and deductions in §§ 628.22 and 628.23. Tier 2 capital elements are:

(1) Instruments (plus related surplus) that meet the following criteria:

(i) The instrument is issued and paid-in, is a common cooperative equity, or is member equity purchased in accordance with paragraph (d)(1)(viii) of this section;

(ii) The instrument is subordinated to general creditors of the System institution;

(iii) The instrument is not secured, not covered by a guarantee of the System institution and not subject to any other arrangement that legally or economically enhances the seniority of the instrument in relation to more senior claims;

(iv) The instrument has a minimum original maturity of at least 5 years. At the beginning of each of the last 5 years of the life of the instrument, the amount that is eligible to be included in tier 2 capital is reduced by 20 percent of the original amount of the instrument (net of redemptions) and is excluded from regulatory capital when the remaining maturity is less than 1 year. In addition, the instrument must not have any terms or features that require, or create significant incentives for, the System institution to redeem the instrument prior to maturity;[4]

(v) The instrument, by its terms, may be called by the System institution only after a minimum of 5 years following issuance, except that the terms of the instrument may allow it to be called sooner upon the occurrence of an event that would preclude the instrument from being included in tier 2 capital, or a tax event. In addition:

(A) The System institution must receive the prior approval of FCA to exercise a call option on the instrument.

(B) The System institution does not create at issuance, through action or communication, an expectation the call option will be exercised.

(C) Prior to exercising the call option, or immediately thereafter, the System institution must either: replace any amount called with an equivalent amount of an instrument that meets the criteria for regulatory capital under this section;[5] or demonstrate to the satisfaction of FCA that following redemption, the System institution would continue to hold an amount of capital that is commensurate with its risk;

(vi) The holder of the instrument must have no contractual right to accelerate payment of principal, dividends, or interest on the instrument, except in the event of a receivership, insolvency, liquidation, or similar proceeding of the System institution;

(vii) The instrument has no credit-sensitive feature, such as a dividend or interest rate that is reset periodically based in whole or in part on the System institution's credit standing, but may have a dividend rate that is adjusted periodically independent of the System institution's credit standing, in relation to general market interest rates or similar adjustments;

(viii) The System institution has not purchased and has not directly or indirectly funded the purchase of the instrument, except that where common cooperative equity instruments are held by a member of the institution in connection with a loan, and the institution funds the acquisition of such instruments, that loan shall not be considered as a direct or indirect funding where:

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[3] Replacement can be concurrent with redemption of existing AT1 capital instruments.

[4] An instrument that by its terms automatically converts into a tier 1 capital instrument prior to five years after issuance complies with the five-year maturity requirement of this criterion.

[5] A System institution may replace tier 2 capital instruments concurrent with the redemption of existing tier 2 capital instruments.

(A) The purpose of the loan is not the purchase of capital instruments of the System institution providing the loan;

(B) The purchase or acquisition of one or more capital instruments of the institution is necessary in order for the beneficiary of the loan to become a member of the System institution; and

(C) The capital instruments are in excess of the statutory minimum stock purchase amount.

(ix) [Reserved]

(x) Redemption of the instrument prior to maturity or repurchase is at the discretion of the System institution and requires the prior approval of the FCA;

(xi) The System institution's capitalization bylaws, or a resolution adopted by its board of directors under § 615.5200(d) of this chapter and re-affirmed by the board on an annual basis, provides that the institution:

(A) Establishes a minimum call, redemption or revolvement period of 5 years for equities included in tier 2 capital; and

(B) Shall not call, redeem, revolve, cancel, or remove any equities included in tier 2 capital without prior approval of the FCA under § 628.20(f).

(2) [Reserved]

(3) ALL up to 1.25 percent of the System institution's total risk-weighted assets not including any amount of the ALL.

(4) [Reserved]

(5) [Reserved]

(6) [Reserved]

(e) *FCA approval of a capital element.* (1) A System institution must receive FCA prior approval to include a capital element (as listed in this section) in its CET1 capital, AT1 capital, or tier 2 capital unless the element is equivalent, in terms of capital quality and ability to absorb losses with respect to all material terms, to a regulatory capital element FCA determined may be included in regulatory capital pursuant to paragraph (e)(3) of this section.

(i) [Reserved]

(ii) [Reserved]

(2) [Reserved]

(3) After determining that a regulatory capital element may be included in a System institution's CET1 capital, AT1 capital, or tier 2 capital, FCA will make its decision publicly available.

(f) *FCA prior approval of capital redemptions and dividends included in tier 1 and tier 2 capital.* (1) Subject to the provisions of paragraphs (f)(5) and (6) of this section, a System institution must obtain the prior approval of the FCA before paying cash dividend payments, cash patronage payments, or redeeming equities included in tier 1 or tier 2 capital, other than term equities redeemed on their maturity date.

(2) At least 30 days prior to the intended action, the System institution must submit a request for approval to the FCA. The FCA's 30-day review period begins on the date on which the FCA receives the request.

(3) The request is deemed to be granted if the FCA does not notify the System institution to the contrary before the end of the 30-day review period.

(4)(i) A System institution may request advance approval to cover several anticipated cash dividend or patronage payments, or equity redemptions, provided that the institution projects sufficient current net income during those periods to support the amount of the cash dividend or patronage payments and equity redemptions. In determining whether to grant advance approval, the FCA will consider:

(A) The reasonableness of the institution's request, including its historical and projected cash dividend and patronage payments and equity redemptions;

(B) The institution's historical trends and current projections for capital growth through earnings retention;

(C) The overall condition of the institution, with particular emphasis on current and projected capital adequacy as described in § 628.10(e); and

(D) Any other information that the FCA deems pertinent to reviewing the institution's request.

(ii) After considering these standards, the FCA may grant advance prior approval of an institution's request to pay cash dividends and patronage or to redeem or revolve equity. Notwithstanding any such approval, an institution may not declare a dividend or patronage payment or redeem or revolve equities if, after such declaration, redemption, or revolvement, the institution would not meet its regulatory capital requirements set forth in this part and part 615 of this chapter.

(5) Subject to any capital distribution restrictions specified in § 628.11, a System institution is deemed to have FCA prior approval for revolvements and redemptions of common cooperative equities, for cash dividend payments on all equities, and for cash patronage payments on all cooperative equities, provided that:

(i) For redemptions or revolvements of common cooperative equities included in CET1 capital or tier 2 capital, other than as provided in paragraph (f)(6) of this section, the institution issued or allocated such equities at least 7 years ago for CET1 capital and at least 5 years ago for tier 2 capital;

(ii) After such cash payments, the dollar amount of the System institution's CET1 capital equals or exceeds the dollar amount of CET1 capital on the same date in the previous calendar year; and

(iii) The System institution continues to comply with all regulatory capital requirements and supervisory or enforcement actions.

(6) The following equities are eligible to be redeemed or revolved under paragraph (f)(5)(i) of this section in less than the applicable minimum required holding period (7 years for CET1 inclusion and 5 years for tier 2 inclusion), provided that the requirements of paragraphs (f)(5)(ii) and (iii) of this section are met:

(i) Equities mandated to be redeemed or retired by a final order of a court of competent jurisdiction;

(ii) Equities held by the estate of a deceased former borrower; and

(iii) Equities that the institution is required to cancel under § 615.5290 of this chapter in connection with a restructuring under part 617 of this chapter.

§ 628.21 [Reserved]

§ 628.22 Regulatory capital adjustments and deductions.

(a) *Regulatory capital deductions from CET1 capital.* A System institution must deduct from the sum of its CET1 capital elements the items set forth in this paragraph (a):

(1) Goodwill, net of associated deferred tax liabilities (DTLs) in accordance with paragraph (e) of this section;

(2) Intangible assets, other than mortgage servicing assets (MSAs), net of associated DTLs in accordance with paragraph (e) of this section;

(3) Deferred tax assets (DTAs) that arise from net operating loss and tax credit carryforwards net of any related valuation allowances and net of DTLs in accordance with paragraph (e) of this section;

(4) Any gain-on-sale in connection with a securitization exposure;

(5) Any defined benefit pension fund net asset, net of any associated DTL in accordance with paragraph (e) of this section, except that, with FCA prior approval, this deduction is not required for any defined benefit pension fund net asset to the extent the institution has

unrestricted and unfettered access to the assets in that fund;

(6) The System institution's allocated equity investment in another System institution; and

(7) [Reserved]

(8) If, without the required prior FCA approval, the System institution redeems or revolves purchased or allocated equities included in its CET1 capital that have been outstanding for less than 7 years, the FCA may take appropriate supervisory or enforcement actions against the institution, which may include requiring the institution to deduct a portion of its purchased and allocated equities from CET1 capital.

(b) [Reserved]

(c) *Deductions from regulatory capital.*[6] (1) [Reserved]

(2) *Corresponding deduction approach.* For purposes of subpart C of this part, the corresponding deduction approach is the methodology used for the deductions from regulatory capital related to purchased equity investments in another System institution (as described in paragraph (c)(5) of this section). Under the corresponding deduction approach, a System institution must make deductions from the component of capital for which the underlying instrument would qualify if it were issued by the System institution itself. If the System institution does not have a sufficient amount of a specific component of capital to effect the required deduction, the shortfall must be deducted according to paragraph (f) of this section.

(i) [Reserved]

(ii) [Reserved]

(iii) [Reserved]

(3) [Reserved]

(4) [Reserved]

(5) *Purchased equity investments in another System institution.* System institutions must deduct all purchased equity investments in another System institution, service corporation, or the Funding Corporation by applying the corresponding deduction approach. The deductions described in this section are net of associated DTLs in accordance with paragraph (e) of this section. With prior written approval of FCA, for the period stipulated by FCA, a System institution is not required to deduct an investment in the capital of another institution in distress if such investment is made to provide financial support to the System institution as determined by FCA.

(d) [Reserved]

(e) *Netting of DTLs against assets subject to deduction.* (1) The netting of DTLs against assets that are subject to deduction under this section is required, if the following conditions are met:

(i) The DTL is associated with the asset; and

(ii) The DTL would be extinguished if the associated asset becomes impaired or is derecognized under GAAP.

(2) A DTL may only be netted against a single asset.

(3) [Reserved]

(4) [Reserved]

(5) A System institution must net DTLs against assets subject to deduction under this section in a consistent manner from reporting period to reporting period.

(f) *Insufficient amounts of a specific regulatory capital component to effect deductions.* Under the corresponding deduction approach, if a System institution does not have a sufficient amount of a specific component of capital to effect the required deduction after completing the deductions required under paragraph (c) of this section, the System institution must deduct the shortfall from the next higher (that is, more subordinated) component of regulatory capital.

(g) *Treatment of assets that are deducted.* A System institution must exclude from total risk-weighted assets any item deducted from regulatory capital under paragraphs (a) and (c) of this section.

(h) [Reserved]

§ 628.23 Limit on inclusion of third-party capital in total (tier 1 and tier 2) capital.

The combined amount of third-party capital instruments that a System institution may include in total (tier 1 and tier 2) capital is equal to the greater of the following:

(a) The then existing limit, if any; or

(b) The lesser of:

(1) Forty percent of total capital, calculated by taking two thirds of the average of the previous 4 quarters of total capital reported on the institution's Call Report filed with the FCA, less any amounts of third-party capital reported in total capital; or

(2) The average of the previous 4 quarters of CET1 capital reported on its Call Report filed with the FCA.

(c) *Treatment of assets that are deducted.* A System institution must exclude from total risk-weighted assets any item deducted from regulatory capital under this section.

§§ 628.24–628.29 [Reserved]

Subpart D—Risk Weighted Assets—Standardized Approach

§ 628.30 Applicability.

(a) This subpart sets forth methodologies for determining risk-weighted assets for purposes of the generally applicable risk-based capital requirements for all System institutions.

(b) [Reserved]

Risk-Weighted Assets for General Credit Risk

§ 628.31 Mechanics for calculating risk-weighted assets for general credit risk.

(a) *General risk-weighting requirements.* A System institution must apply risk weights to its exposures as follows:

(1) A System institution must determine the exposure amount of each on-balance sheet exposure, each OTC derivative contract, and each off-balance sheet commitment, trade and transaction-related contingency, guarantee, repo-style transaction, financial standby letter of credit, forward agreement, or other similar transaction that is not:

(i) An unsettled transaction subject to § 628.38;

(ii) A cleared transaction subject to § 628.35;

(iii) [Reserved]

(iv) A securitization exposure subject to §§ 628.41 through 628.45; or

(v) An equity exposure (other than an equity OTC derivative contract) subject to §§ 628.51 through 628.53.

(2) The System institution must multiply each exposure amount by the risk weight appropriate to the exposure based on the exposure type or counterparty, eligible guarantor, or financial collateral to determine the risk-weighted asset amount for each exposure.

(b) Total risk-weighted assets for general credit risk equals the sum of the risk-weighted asset amounts calculated under this section.

§ 628.32 General risk weights.

(a) *Sovereign exposures*—(1) *Exposures to the U.S. Government.* (i) Notwithstanding any other requirement in this subpart, a System institution must assign a 0-percent risk weight to:

(A) An exposure to the U.S. Government, its central bank, or a U.S. Government agency; and

(B) The portion of an exposure that is directly and unconditionally guaranteed by the U.S. Government, its central bank, or a U.S. Government agency. This includes a deposit or other exposure, or the portion of a deposit or other exposure that is insured or otherwise unconditionally guaranteed by the Federal Deposit Insurance Corporation or National Credit Union Administration.

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[6] The System institution must calculate amounts deducted under paragraphs (c) through (f) of this section and § 628.23 after it calculates the amount of ALL includable in tier 2 capital under § 628.20(d)(3).

(ii) A System institution must assign a 20-percent risk weight to the portion of an exposure that is conditionally guaranteed by the U.S. Government, its central bank, or a U.S. Government agency. This includes an exposure, or the portion of an exposure, that is conditionally guaranteed by the Federal Deposit Insurance Corporation or National Credit Union Administration.

(2) *Other sovereign exposures.* In accordance with Table 1 to § 628.32, a System institution must assign a risk weight to a sovereign exposure based on the Country Risk Classification (CRC) applicable to the sovereign or the sovereign's Organization for Economic Cooperation and Development (OECD) membership status if there is no CRC applicable to the sovereign.

TABLE 1 TO § 628.32—RISK WEIGHTS FOR SOVEREIGN EXPOSURES

	Risk weight (in percent)
CRC:	
0–1	0
2	20
3	50
4–6	100
7	150
OECD Member with no CRC	0
Non-OECD Member with no CRC	100
Sovereign Default	150

(3) *Certain sovereign exposures.* Notwithstanding paragraph (a)(2) of this section, a System institution may assign to a sovereign exposure a risk weight that is lower than the applicable risk weight in Table 1 to § 628.32 if:

(i) The exposure is denominated in the sovereign's currency;

(ii) The System institution has at least an equivalent amount of liabilities in that currency; and

(iii) The risk weight is not lower than the risk weight that the sovereign allows banking organizations under its jurisdiction to assign to the same exposures to the sovereign.

(4) *Exposures to a non-OECD member sovereign with no CRC.* Except as provided in paragraphs (a)(3), (5), and (6) of this section, a System institution must assign a 100-percent risk weight to a sovereign exposure if the sovereign does not have a CRC.

(5) *Exposures to an OECD member sovereign with no CRC.* Except as provided in paragraph (a)(6) of this section, a System institution must assign a 0-percent risk weight to an exposure to a sovereign that is a member of the OECD if the sovereign does not have a CRC.

(6) *Sovereign default.* A System institution must assign a 150-percent risk weight to a sovereign exposure immediately upon determining that an event of sovereign default has occurred, or if an event of sovereign default has occurred during the previous 5 years.

(b) *Certain supranational entities and multilateral development banks (MDBs).* A System institution must assign a 0-percent risk weight to an exposure to the Bank for International Settlements, the European Central Bank, the European Commission, the International Monetary Fund, or an MDB.

(c) *Exposures to Government-sponsored enterprises (GSEs).* (1) A System institution must assign a 20-percent risk weight to an exposure to a GSE other than an equity exposure or preferred stock.

(2) A System institution must assign a 100-percent risk weight to preferred stock issued by a non-System GSE.

(3) Purchased equity investments (including preferred stock investments) in other System institutions do not receive a risk weight, because they are deducted from capital in accordance with § 628.22.

(d) *Exposures to depository institutions, foreign banks, and credit unions*—(1) *Exposures to U.S. depository institutions and credit unions.* A System institution must assign a 20-percent risk weight to an exposure to a depository institution or credit union that is organized under the laws of the United States or any state thereof, except as otherwise provided in this paragraph (d). This risk weight applies to an exposure a System bank has to another financing institution (OFI) that is a depository institution or credit union organized under the laws of the United States or any state thereof or is owned and controlled by such an entity that guarantees the exposure. If the OFI exposure does not satisfy these requirements, it must be assigned a risk weight as a corporate exposure pursuant to paragraph (f)(1)(ii) or (f)(2) of this section.

(2) *Exposures to foreign banks.* (i) Except as otherwise provided under paragraph (d)(2)(iv) of this section, a System institution must assign a risk weight to an exposure to a foreign bank, in accordance with Table 2 to § 628.32, based on the CRC rating that corresponds to the foreign bank's home country or the OECD membership status of the foreign bank's home country if there is no CRC applicable to the foreign bank's home country.

TABLE 2 TO § 628.32—RISK WEIGHTS FOR EXPOSURES TO FOREIGN BANKS

	Risk weight (in percent)
CRC:	
0–1	20
2	50
3	100
4–7	150
OECD Member with No CRC	20
Non-OECD with No CRC	100
Sovereign Default	150

(ii) A System institution must assign a 20-percent risk weight to an exposure to a foreign bank whose home country is a member of the OECD and does not have a CRC.

(iii) A System institution must assign a 100-percent risk weight to an exposure to a foreign bank whose home country is not a member of the OECD and does not have a CRC, with the exception of self-liquidating, trade-related contingent items that arise from the movement of goods, and that have a maturity of 3 months or less, which may be assigned a 20-percent risk weight.

(iv) A System institution must assign a 150-percent risk weight to an exposure to a foreign bank immediately upon determining that an event of sovereign default has occurred in the bank's home country, or if an event of sovereign default has occurred in the foreign bank's home country during the previous 5 years.

(3) [Reserved]

(e) *Exposures to public sector entities (PSEs)*—(1) *Exposures to U.S. PSEs.* (i) A System institution must assign a 20-percent risk weight to a general obligation exposure to a PSE that is organized under the laws of the United States or any state or political subdivision thereof.

(ii) A System institution must assign a 50-percent risk weight to a revenue obligation exposure to a PSE that is organized under the laws of the United States or any state or political subdivision thereof.

(2) *Exposures to foreign PSEs.* (i) Except as provided in paragraphs (e)(1) and (3) of this section, a System institution must assign a risk weight to a general obligation exposure to a foreign PSE, in accordance with Table 3 to § 628.32, based on the CRC that corresponds to the PSE's home country or the OECD membership status of the PSE's home country if there is no CRC applicable to the PSE's home country.

(ii) Except as provided in paragraphs (e)(1) and (3) of this section, a System institution must assign a risk weight to a revenue obligation exposure to a foreign PSE, in accordance with Table 4 to § 628.32, based on the CRC that corresponds to the PSE's home country; or the OECD membership status of the PSE's home country if there is no CRC applicable to the PSE's home country.

(3) A System institution may assign a lower risk weight than would otherwise apply under Tables 3 and 4 to § 628.32 to an exposure to a foreign PSE if:

(i) The PSE's home country supervisor allows banks under its jurisdiction to assign a lower risk weight to such exposures; and

(ii) The risk weight is not lower than the risk weight that corresponds to the PSE's home country in accordance with Table 1 to § 628.32.

TABLE 3 TO § 628.32—RISK WEIGHTS FOR NON-U.S. PSE GENERAL OBLIGATIONS

	Risk weight (in percent)
CRC:	
0–1	20
2	50
3	100
4–7	150
OECD Member with No CRC	20
Non-OECD Member with No CRC	100
Sovereign Default	150

TABLE 4 TO § 628.32—RISK WEIGHTS FOR NON-U.S. PSE REVENUE OBLIGATIONS

	Risk weight (in percent)
CRC:	
0–1	50
2–3	100
4–7	150
OECD Member with No CRC	50
Non-OECD Member with No CRC	100
Sovereign Default	150

(4) *Exposures to PSEs from an OECD member sovereign with no CRC.* (i) A System institution must assign a 20-percent risk weight to a general obligation exposure to a PSE whose home country is a OECD member sovereign with no CRC.

(ii) A System institution must assign a 50-percent risk weight to a revenue obligation exposure to a PSE whose country is an OECD member sovereign with no CRC.

(5) *Exposures to PSEs whose home country is not an OECD member sovereign with no CRC.* A System institution must assign a 100-percent risk weight to an exposure to a PSE whose home country is not a member of the OECD and does not have a CRC.

(6) A System institution must assign a 150-percent risk weight to a PSE exposure immediately upon determining that an event of sovereign default has occurred in a PSE's home country or if an event of sovereign default has occurred in the PSE's home country during the previous 5 years.

(f) *Corporate exposures*—(1) *100-percent risk weight.* Except as provided in paragraph (f)(2) of this section, a System institution must assign a 100-percent risk weight to all its corporate exposures. Assets assigned a risk weight under this provision include:

(i) Borrower loans such as agricultural loans and consumer loans, regardless of the corporate form of the borrower, unless those loans qualify for different risk weights under other provisions of this subpart D;

(ii) System bank exposures to OFIs that do not satisfy the requirements for a 20-percent risk weight pursuant to paragraph (d)(1) of this section or a 50-percent risk weight pursuant to paragraph (f)(2) of this section; and

(iii) Premises, fixed assets, and other real estate owned.

(2) *50-percent risk weight.* Unless the OFI satisfies the requirements for a 20-percent risk weight pursuant to paragraph (d)(1) of this section, a System institution must assign a 50-percent risk weight to an exposure to an OFI that satisfies at least one of the following requirements:

(i) The OFI is investment grade or is owned and controlled by an investment grade entity that guarantees the exposure; or

(ii) The OFI meets capital, risk identification and control, and operational standards similar to the OFIs identified in paragraph (d)(1) of this section.

(g) *Residential mortgage exposures.* (1) A System institution must assign a 50-percent risk weight to a first-lien residential mortgage exposure that:

(i) Is secured by a property that is either owner-occupied or rented;

(ii) Is made in accordance with prudent underwriting standards suitable for residential property, including standards relating to the loan amount as a percent of the appraised value of the property;

(iii) Is not 90 days or more past due or carried in nonaccrual status; and

(iv) Is not restructured or modified.

(2) A System institution must assign a 100-percent risk weight to a first-lien residential mortgage exposure that does not meet the criteria in paragraph (g)(1) of this section, and to junior-lien residential mortgage exposures.

(3) For the purpose of this paragraph (g), if a System institution holds the first-lien and junior-lien(s) residential mortgage exposures, and no other party holds an intervening lien, the System institution must combine the exposures and treat them as a single first-lien residential mortgage exposure.

(4) A loan modified or restructured solely pursuant to the U.S. Treasury's Home Affordable Mortgage Program is not modified or restructured for purposes of this section.

(h) [Reserved]

(i) [Reserved]

(j) [Reserved]

(k) *Past due and nonaccrual exposures.* Except for a sovereign exposure or a residential mortgage exposure, a System institution must determine a risk weight for an exposure that is 90 days or more past due or in nonaccrual status according to the requirements set forth in this paragraph (k).

(1) A System institution must assign a 150-percent risk weight to the portion of the exposure that is not guaranteed or that is not secured by financial collateral.

(2) A System institution may assign a risk weight to the guaranteed portion of a past due or nonaccrual exposure based on the risk weight that applies under § 628.36 if the guarantee or credit derivative meets the requirements of that section.

(3) A System institution may assign a risk weight to the portion of a past due or nonaccrual exposure that is collateralized by financial collateral based on the risk weight that applies under § 628.37 if the financial collateral meets the requirements of that section.

(l) *Other assets.* (1) A System institution must assign a 0-percent risk weight to cash owned and held in all offices of the System institution, in transit, or in accounts at a depository institution or a Federal Reserve Bank; to gold bullion held in a depository institution's vaults on an allocated basis, to the extent the gold bullion assets are offset by gold bullion liabilities; and to exposures that arise from the settlement of cash transactions (such as equities, fixed income, spot foreign exchange (FX) and spot commodities) with a central counterparty where there is no assumption of ongoing counterparty credit risk by the central counterparty after settlement of the trade.

(2) A System institution must assign a 20-percent risk weight to cash items in the process of collection.

(3) A System institution must assign a 100-percent risk weight to deferred tax assets (DTAs) arising from temporary differences in relation to net operating loss carrybacks.

(4) A System institution must assign a 100-percent risk weight to all MSAs.

(5) A System institution must assign a 100-percent risk weight to all assets that are not specifically assigned a different risk weight under this subpart and that are not deducted from tier 1 or tier 2 capital pursuant to § 628.22.

(6) [Reserved]

§ 628.33 Off-balance sheet exposures.

(a) *General.* (1) A System institution must calculate the exposure amount of an off-balance sheet exposure using the credit conversion factors (CCFs) in paragraph (b) of this section.

(2) Where a System institution commits to provide a commitment, the System institution may apply the lower of the two applicable CCFs.

(3) Where a System institution provides a commitment structured as a syndication or participation, the System institution is only required to calculate the exposure amount for its pro rata share of the commitment.

(4) Where a System institution provides a commitment, enters into a repurchase agreement, or provides a credit enhancing representation and warranty, and such commitment, repurchase agreement, or credit-enhancing representation and warranty is not a securitization exposure, the exposure amount shall be no greater than the maximum contractual amount of the commitment, repurchase agreement, or credit-enhancing representation and warranty, as applicable.

(5) The exposure amount of a System bank's commitment to an association or OFI is the difference between the association's or OFI's maximum credit limit with the System bank (as established by the general financing agreement or promissory note, as required by § 614.4125(d) of this chapter), and the amount the association or OFI has borrowed from the System bank.

(b) *Credit conversion factors*—(1) *Zero-percent (0%) CCF.* A System institution must apply a 0-percent CCF to a commitment that is unconditionally cancelable by the System institution.

(2) *Twenty-percent (20%) CCF.* A System institution must apply a 20-percent CCF to the amount of:

(i) Commitments, other than a System bank's commitment to an association or OFI, with an original maturity of 14 months or less that are not unconditionally cancelable by the System institution.

(ii) Self-liquidating, trade-related contingent items that arise from the movement of goods, with an original maturity of 14 months or less.

(iii) A System bank's commitment to an association or OFI that is not unconditionally cancelable by the System bank, regardless of maturity.

(3) *Fifty-percent (50%) CCF.* A System institution must apply a 50-percent CCF to the amount of:

(i) Commitments, other than a System bank's commitment to an association or OFI, with an original maturity of more than 14 months that are not unconditionally cancelable by the System institution.

(ii) Transaction-related contingent items, including performance bonds, bid bonds, warranties, and performance standby letters of credit.

(4) *One hundred-percent (100%) CCF.* A System institution must apply a 100-percent CCF to the following off-balance sheet items and other similar transactions:

(i) Guarantees;

(ii) Repurchase agreements (the off-balance sheet component of which equals the sum of the current fair values of all positions the System institution has sold subject to repurchase);

(iii) Credit-enhancing representations and warranties that are not securitization exposures;

(iv) Off-balance sheet securities lending transactions (the off-balance sheet component of which equals the sum of the current fair values of all positions the System institution has lent under the transaction);

(v) Off-balance sheet securities borrowing transactions (the off-balance sheet component of which equals the sum of the current fair values of all non-cash positions the System institution has posted as collateral under the transaction);

(vi) Financial standby letters of credit; and

(vii) Forward agreements.

§ 628.34 OTC derivative contracts.

(a) *Exposure amount*—(1) *Single OTC derivative contract.* Except as modified by paragraph (b) of this section, the exposure amount for a single OTC derivative contract that is not subject to a qualifying master netting agreement is equal to the sum of the System institution's current credit exposure and potential future credit exposure (PFE) on the OTC derivative contract.

(i) *Current credit exposure.* The current credit exposure for a single OTC derivative contract is the greater of the mark-to-fair value of the OTC derivative contract or 0.

(ii) *PFE.* (A) The PFE for a single OTC derivative contract, including an OTC derivative contract with a negative mark-to-fair value, is calculated by multiplying the notional principal amount of the OTC derivative contract by the appropriate conversion factor in Table 1 to § 628.34.

(B) For purposes of calculating either the PFE under this paragraph or the gross PFE under paragraph (a)(2) of this section for exchange rate contracts and other similar contracts in which the notional principal amount is equivalent to the cash flows, notional principal amount is the net receipts to each party falling due on each value date in each currency.

(C) For an OTC derivative contract that does not fall within one of the specified categories in Table 1 to § 628.34, the PFE must be calculated using the appropriate "other" conversion factor.

(D) A System institution must use an OTC derivative contract's effective notional principal amount (that is, the apparent or stated notional principal amount multiplied by any multiplier in the OTC derivative contract) rather than the apparent or stated notional principal amount in calculating PFE.

(E) The PFE of the protection provider of a credit derivative is capped at the net present value of the amount of unpaid premiums.

TABLE 1 TO § 628.34—CONVERSION FACTOR MATRIX FOR DERIVATIVE CONTRACTS [1]

Remaining maturity [2]	Interest rate	Foreign exchange rate and gold	Credit (investment grade reference asset) [3]	Credit (non-investment-grade reference asset)	Equity	Precious metals (except gold)	Other
One (1) year or less	0.00	0.01	0.05	0.10	0.06	0.07	0.10
Greater than one (1) year and less than or equal to five (5) years	0.005	0.05	0.05	0.10	0.08	0.07	0.12
Greater than five (5) years	0.015	0.075	0.05	0.10	0.10	0.08	0.15

[1] For a derivative contract with multiple exchanges of principal, the conversion factor is multiplied by the number of remaining payments in the derivative contract.

[2] For an OTC derivative contract that is structured such that on specified dates any outstanding exposure is settled and the terms are reset so that the fair value of the contract is 0, the remaining maturity equals the time until the next reset date. For an interest rate derivative contract with a remaining maturity of greater than 1 year that meets these criteria, the minimum conversion factor is 0.005.

[3] A System institution must use the column labeled "Credit (investment-grade reference asset)" for a credit derivative whose reference asset is an outstanding unsecured long-term debt security without credit enhancement that is investment grade. A System institution must use the column labeled "Credit (non-investment-grade reference asset)" for all other credit derivatives.

(2) *Multiple OTC derivative contracts subject to a qualifying master netting agreement.* Except as modified by paragraph (b) of this section, the exposure amount for multiple OTC derivative contracts subject to a qualifying master netting agreement is equal to the sum of the net current credit exposure and the adjusted sum of the PFE amounts for all OTC derivative contracts subject to the qualifying master netting agreement.

(i) *Net current credit exposure.* The net current credit exposure is the greater of the net sum of all positive and negative mark-to-fair values of the individual OTC derivative contracts subject to the qualifying master netting agreement or 0.

(ii) *Adjusted sum of the PFE amounts.* The adjusted sum of the PFE amounts, Anet, is calculated as:

$$A_{net} = (0.4 \times A_{gross}) + (0.6 \times NGR \times A_{gross})$$

Where:

A_{gross} = the gross PFE (that is, the sum of the PFE amounts (as determined under paragraph (a)(1)(ii) of this section for each individual derivative contract subject to the qualifying master netting agreement); and

Net-to-gross Ratio (NGR) = the ratio of the net current credit exposure to the gross current credit exposure. In calculating the NGR, the gross current credit exposure equals the sum of the positive current credit exposures (as determined under paragraph (a)(1)(i) of this section) of all individual derivative contracts subject to the qualifying master netting agreement.

(b) *Recognition of credit risk mitigation of collateralized OTC derivative contracts.* (1) A System institution may recognize the credit risk mitigation benefits of financial collateral that secures an OTC derivative contract or multiple OTC derivative contracts subject to a qualifying master netting agreement (netting set) by using the simple approach in § 628.37(b).

(2) Alternatively, if the financial collateral securing a contract or netting set described in paragraph (b)(1) of this section is marked-to-fair value on a daily basis and subject to a daily margin maintenance requirement, a System institution may recognize the credit risk mitigation benefits of financial collateral that secures the contract or netting set by using the collateral haircut approach in § 628.37(c).

(c) *Counterparty credit risk for OTC credit derivatives*—(1) *Protection purchasers.* A System institution that purchases an OTC credit derivative that is recognized under § 628.36 as a credit risk mitigant is not required to compute a separate counterparty credit risk capital requirement under § 628.32 provided that the System institution does so consistently for all such credit derivatives. The System institution must either include all or exclude all such credit derivatives that are subject to a qualifying master netting agreement from any measure used to determine counterparty credit risk exposure to all relevant counterparties for risk-based capital purposes.

(2) *Protection providers.* (i) A System institution that is the protection provider under an OTC credit derivative must treat the OTC credit derivative as an exposure to the underlying reference asset. The System institution is not required to compute a counterparty credit risk capital requirement for the OTC credit derivative under § 628.32, provided that this treatment is applied consistently for all such OTC credit derivatives. The System institution must either include all or exclude all such OTC credit derivatives that are subject to a qualifying master netting agreement from any measure used to determine counterparty credit risk exposure.

(ii) The provisions of paragraph (c)(2) of this section apply to all relevant counterparties for risk-based capital purposes.

(d) *Counterparty credit risk for OTC equity derivatives.* (1) A System institution must treat an OTC equity derivative contract as an equity exposure and compute a risk-weighted asset amount for the OTC equity derivative contract under §§ 628.51 through 628.53.

(2) [Reserved]

(3) If the System institution risk weights the contract under the Simple Risk-Weight Approach (SRWA) in § 628.52, the System institution may choose not to hold risk-based capital against the counterparty credit risk of the OTC equity derivative contract, as long as it does so for all such contracts. Where the OTC equity derivative contracts are subject to a qualifying master netting agreement, a System institution using the SRWA must either include all or exclude all of the contracts from any measure used to determine counterparty credit risk exposure.

(e) [Reserved]

§ 628.35 Cleared transactions.

(a) *General requirements*—(1) *Clearing member clients.* A System institution that is a clearing member client must use the methodologies described in paragraph (b) of this section to calculate risk-weighted assets for a cleared transaction.

(2) [Reserved]

(b) *Clearing member client System institutions*—(1) *Risk-weighted assets for cleared transactions.* (i) To determine the risk-weighted asset amount for a cleared transaction, a System institution that is a clearing member client must multiply the trade exposure amount for the cleared transaction, calculated in accordance with paragraph (b)(2) of this section, by the risk weight appropriate for the cleared transaction, determined in accordance with paragraph (b)(3) of this section.

(ii) A clearing member client System institution's total risk-weighted assets for cleared transactions is the sum of the risk-weighted asset amounts for all its cleared transactions.

(2) *Trade exposure amount.* (i) For a cleared transaction that is either a derivative contract or netting set of derivative contracts, the trade exposure amount equals:

(A) The exposure amount for the derivative contract or netting set of derivative contracts, calculated using the current exposure method (CEM) for OTC derivative contracts under § 628.34; plus

(B) The fair value of the collateral posted by the clearing member client System institution and held by the central counterparty (CCP), clearing member, or custodian in a manner that is not bankruptcy remote.

(ii) For a cleared transaction that is a repo-style transaction, the trade exposure amount equals:

(A) The exposure amount for the repo-style transaction calculated using the collateral haircut methodology under § 628.37(c); plus

(B) The fair value of the collateral posted by the clearing member client System institution and held by the CCP or a clearing member in a manner that is not bankruptcy remote.

(3) *Cleared transaction risk weights.* (i) For a cleared transaction with a qualifying CCP (QCCP), a clearing member client System institution must apply a risk weight of:

(A) Two (2) percent if the collateral posted by the System institution to the QCCP or clearing member is subject to an arrangement that prevents any losses to the clearing member client System institution due to the joint default or a concurrent insolvency, liquidation, or receivership proceeding of the clearing member and any other clearing member clients of the clearing member; and the clearing member client System institution has conducted sufficient legal review to conclude with a well-founded basis (and maintains sufficient written documentation of that legal review) that in the event of a legal challenge (including one resulting from default or from liquidation, insolvency, or receivership proceeding) the relevant court and administrative authorities would find the arrangements to be legal, valid, binding and enforceable under the law of the relevant jurisdictions; or

(B) Four (4) percent if the requirements of paragraph (b)(3)(i)(A) of this section are not met.

(ii) For a cleared transaction with a CCP that is not a QCCP, a clearing member client System institution must apply the risk weight appropriate for the CCP according to § 628.32.

(4) *Collateral.* (i) Notwithstanding any other requirements in this section, collateral posted by a clearing member client System institution that is held by a custodian (in its capacity as custodian) in a manner that is bankruptcy remote from the CCP, the custodian, clearing member and other clearing member clients of the clearing member, is not subject to a capital requirement under this section.

(ii) A clearing member client System institution must calculate a risk-weighted asset amount for any collateral provided to a CCP, clearing member, or custodian in connection with a cleared transaction in accordance with the requirements under § 628.32.

(c) [Reserved]

(d) [Reserved]

§ 628.36 Guarantees and credit derivatives: substitution treatment.

(a) *Scope*—(1) *General.* A System institution may recognize the credit risk mitigation benefits of an eligible guarantee or eligible credit derivative by substituting the risk weight associated with the protection provider for the risk weight assigned to an exposure, as provided under this section.

(2) This section applies to exposures for which:

(i) Credit risk is fully covered by an eligible guarantee or eligible credit derivative; or

(ii) Credit risk is covered on a pro rata basis (that is, on a basis in which the System institution and the protection provider share losses proportionately) by an eligible guarantee or eligible credit derivative.

(3) Exposures on which there is a tranching of credit risk (reflecting at least two different levels of seniority) generally are securitization exposures subject to §§ 628.41 through 628.45.

(4) If multiple eligible guarantees or eligible credit derivatives cover a single exposure described in this section, a System institution may treat the hedged exposure as multiple separate exposures each covered by a single eligible guarantee or eligible credit derivative and may calculate a separate risk-weighted asset amount for each separate exposure as described in paragraph (c) of this section.

(5) If a single eligible guarantee or eligible credit derivative covers multiple hedged exposures described in paragraph (a)(2) of this section, a System institution must treat each hedged exposure as covered by a separate eligible guarantee or eligible credit derivative and must calculate a separate risk-weighted asset amount for each exposure as described in paragraph (c) of this section.

(b) *Rules of recognition.* (1) A System institution may only recognize the credit risk mitigation benefits of eligible guarantees and eligible credit derivatives.

(2) A System institution may only recognize the credit risk mitigation benefits of an eligible credit derivative to hedge an exposure that is different from the credit derivative's reference exposure used for determining the derivative's cash settlement value, deliverable obligation, or occurrence of a credit event if:

(i) The reference exposure ranks *pari passu* with, or is subordinated to, the hedged exposure; and

(ii) The reference exposure and the hedged exposure are to the same legal entity, and legally enforceable cross-default or cross-acceleration clauses are in place to ensure payments under the credit derivative are triggered when the obligated party of the hedged exposure fails to pay under the terms of the hedged exposure.

(c) *Substitution approach*—(1) *Full coverage.* If an eligible guarantee or eligible credit derivative meets the conditions in paragraphs (a) and (b) of this section and the protection amount (P) of the guarantee or credit derivative is greater than or equal to the exposure amount of the hedged exposure, a System institution may recognize the guarantee or credit derivative in determining the risk-weighted asset amount for the hedged exposure by substituting the risk weight applicable to the guarantor or credit derivative protection provider under § 628.32 for the risk weight assigned to the exposure.

(2) *Partial coverage.* If an eligible guarantee or eligible credit derivative meets the conditions in §§ 628.36(a) and 628.37(b) and the protection amount (P) of the guarantee or credit derivative is less than the exposure amount of the hedged exposure, the System institution must treat the hedged exposure as two separate exposures (protected and unprotected) in order to recognize the credit risk mitigation benefit of the guarantee or credit derivative.

(i) The System institution may calculate the risk-weighted asset amount for the protected exposure under § 628.32, where the applicable risk weight is the risk weight applicable to the guarantor or credit derivative protection provider.

(ii) The System institution must calculate the risk-weighted asset amount for the unprotected exposure under § 628.32, where the applicable risk weight is that of the unprotected portion of the hedged exposure.

(iii) The treatment provided in this section is applicable when the credit risk of an exposure is covered on a partial pro rata basis and may be applicable when an adjustment is made to the effective notional amount of the guarantee or credit derivative under paragraph (d), (e), or (f) of this section.

(d) *Maturity mismatch adjustment.* (1) A System institution that recognizes an eligible guarantee or eligible credit derivative in determining the risk-weighted asset amount for a hedged exposure must adjust the effective notional amount of the credit risk mitigant to reflect any maturity mismatch between the hedged exposure and the credit risk mitigant.

(2) A maturity mismatch occurs when the residual maturity of a credit risk mitigant is less than that of the hedged exposure(s).

(3) The residual maturity of a hedged exposure is the longest possible remaining time before the obligated party of the hedged exposure is scheduled to fulfill its obligation on the hedged exposure. If a credit risk mitigant has embedded options that may reduce its term, the System institution (protection purchaser) must use the shortest possible residual maturity for the credit risk mitigant. If a call is at the discretion of the protection provider, the residual maturity of the credit risk mitigant is at the first call date. If the call is at the discretion of the System institution (protection purchaser), but the terms of the arrangement at origination of the credit risk mitigant contain a positive incentive for the System institution to call the transaction before contractual maturity, the remaining time to the first call date is the residual maturity of the credit risk mitigant.

(4) A credit risk mitigant with a maturity mismatch may be recognized only if its original maturity is greater than or equal to 1 year and its residual maturity is greater than 3 months.

(5) When a maturity mismatch exists, the System institution must apply the following adjustment to reduce the effective notional amount of the credit risk mitigant:

$$P_m = E \times [(t - 0.25)/(T - 0.25)]$$

Where:

P_m = effective notional amount of the credit risk mitigant, adjusted for maturity mismatch;
E = effective notional amount of the credit risk mitigant;
t = the lesser of T or the residual maturity of the credit risk mitigant, expressed in years; and
T = the lesser of 5 or the residual maturity of the hedged exposure, expressed in years.

(e) *Adjustment for credit derivatives without restructuring as a credit event.* If a System institution recognizes an eligible credit derivative that does not include as a credit event a restructuring of the hedged exposure involving forgiveness or postponement of principal, interest, or fees that results in a credit loss event (that is, a charge-off, specific provision, or other similar debit to the profit and loss account), the System institution must apply the following adjustment to reduce the effective notional amount of the credit derivative:

$$P_r = P_m \times 0.60$$

Where:

P_r = effective notional amount of the credit risk mitigant, adjusted for lack of restructuring event (and maturity mismatch, if applicable); and
P_m = effective notional amount of the credit risk mitigant (adjusted for maturity mismatch, if applicable).

(f) *Currency mismatch adjustment.* (1) If a System institution recognizes an eligible guarantee or eligible credit derivative that is denominated in a currency different from that in which the hedged exposure is denominated, the System institution must apply the following formula to the effective notional amount of the guarantee or credit derivative:

$$P_c = P_r \times (1 - H_{fx})$$

Where:

P_c = effective notional amount of the credit risk mitigant, adjusted for currency mismatch (and maturity mismatch and lack of restructuring event, if applicable);
P_r = effective notional amount of the credit risk mitigant (adjusted for maturity mismatch and lack of restructuring event, if applicable); and
H_{fx} = haircut appropriate for the currency mismatch between the credit risk mitigant and the hedged exposure.

(2) A System institution must set H_{fx} equal to 8 percent.

(3) A System institution must adjust H_{fx} calculated in paragraph (f)(2) of this section upward if the System institution revalues the guarantee or credit derivative less frequently than once every 10 business days using the following square root of time formula:

$$H_{FX} = 8\% \sqrt{\frac{T_M}{10}},$$

Where T_M equals the greater of 10 or the number of days between revaluation.

§ 628.37 Collateralized transactions.

(a) *General.* (1) To recognize the risk-mitigating effects of financial collateral, a System institution may use:

(i) The simple approach in paragraph (b) of this section for any exposure.

(ii) The collateral haircut approach in paragraph (c) of this section for repo-style transactions, eligible margin loans, collateralized derivative contracts, and single-product netting sets of such transactions.

(2) A System institution may use any approach described in this section that is valid for a particular type of exposure or transaction; however, it must use the same approach for similar exposures or transactions.

(b) *The simple approach*—(1) *General requirements.* (i) A System institution may recognize the credit risk mitigation benefits of financial collateral that secures any exposure.

(ii) To qualify for the simple approach, the financial collateral must meet the following requirements:

(A) The collateral must be subject to a collateral agreement for at least the life of the exposure;

(B) The collateral must be revalued at least every 6 months; and

(C) The collateral (other than gold) and the exposure must be denominated in the same currency.

(2) *Risk-weight substitution.* (i) A System institution may apply a risk weight to the portion of an exposure that is secured by the fair value of financial collateral (that meets the requirements of paragraph (b)(1) of this section) based on the risk weight assigned to the collateral under § 628.32. For repurchase agreements, reverse repurchase agreements, and securities lending and borrowing transactions, the collateral is the instruments, gold, and cash the System institution has borrowed, purchased subject to resale, or taken as collateral from the counterparty under the transaction. Except as provided in paragraph (b)(3) of this section, the risk weight assigned to the collateralized portion of the exposure may not be less than 20 percent.

(ii) A System institution must apply a risk weight to the unsecured portion of the exposure based on the risk weight assigned to the exposure under this subpart.

(3) *Exceptions to the 20-percent risk-weight floor and other requirements.* Notwithstanding paragraph (b)(2)(i) of this section:

(i) A System institution may assign a 0-percent risk weight to an exposure to an OTC derivative contract that is marked-to-fair on a daily basis and subject to a daily margin maintenance requirement, to the extent the contract is collateralized by cash on deposit.

(ii) A System institution may assign a 10-percent risk weight to an exposure to an OTC derivative contract that is marked-to-fair value daily and subject to a daily margin maintenance requirement, to the extent that the contract is collateralized by an exposure to a sovereign that qualifies for a 0-percent risk weight under § 628.32.

(iii) A System institution may assign a 0-percent risk weight to the collateralized portion of an exposure where:

(A) The financial collateral is cash on deposit; or

(B) The financial collateral is an exposure to a sovereign that qualifies for a 0-percent risk weight under § 628.32, and the System institution has discounted the fair value of the collateral by 20 percent.

(c) *Collateral haircut approach*—(1) *General.* A System institution may recognize the credit risk mitigation benefits of financial collateral that secures an eligible margin loan, repo-style transaction, collateralized derivative contract, or single-product netting set of such transactions by using the standard supervisory haircuts in paragraph (c)(3) of this section.

(2) *Exposure amount equation.* A System institution must determine the exposure amount for an eligible margin loan, repo-style transaction, collateralized derivative contract, or a single-product netting set of such transactions by setting the exposure amount equal to max:

$$\{0, [(\Sigma E - \Sigma C) + \Sigma(E_s \times H_s) + \Sigma(E_{fx} \times H_{fx})]\}$$

Where:

ΣE = for eligible margin loans and repo-style transactions and netting sets thereof, the value of the exposure (the sum of the current fair values of all instruments, gold, and cash the System institution has lent, sold subject to repurchase, or posted as collateral to the counterparty under the transaction (or netting set)); and

ΣE = for collateralized derivative contracts and netting sets thereof, the exposure amount of the OTC derivative contract (or netting set) calculated under § 628.34(c) or (d).

ΣC = the value of the collateral (the sum of the current fair values of all instruments, gold and cash the System institution has borrowed, purchased subject to resale, or taken as collateral from the counterparty under the transaction (or netting set));

E_s = the absolute value of the net position in a given instrument or in gold (where the net position in the instrument or gold equals the sum of the current fair values of the instrument or gold the System institution has lent, sold subject to repurchase, or posted as collateral to the counterparty minus the sum of the current fair values of that same instrument or gold the System institution has borrowed, purchased subject to resale, or taken as collateral from the counterparty);

H_s = the fair value price volatility haircut appropriate to the instrument or gold referenced in Es;

E_{fx} = the absolute value of the net position of instruments and cash in a currency that is different from the settlement currency (where the net position in a given currency equals the sum of the current fair values of any instruments or cash in the currency the System institution has lent, sold subject to repurchase, or posted as collateral to the counterparty minus the sum of the current fair values of any instruments or cash in the currency the System institution has borrowed, purchased subject to resale, or taken as collateral from the counterparty); and

H_{fx} = the haircut appropriate to the mismatch between the currency referenced in E_{fx} and the settlement currency.

(3) *Standard supervisory haircuts.* (i) A System institution must use the haircuts for fair value price volatility (Hs) provided in Table 1 to § 628.37, as adjusted in certain circumstances in accordance with the requirements of paragraphs (c)(3)(iii) and (iv) of this section:

TABLE 1 TO § 628.37—STANDARD SUPERVISORY MARKET PRICE VOLATILITY HAIRCUT [1]

Residual maturity	Haircut (in percent) assigned based on						Investment grade securitization exposures (in percent)
	Sovereign issuers risk weight under § 628.32 [2]			Non-sovereign issuers risk weight under § 628.32			
	Zero	20% or −50%	100%	20%	50%	100%	
Less than or equal to 1 year	0.5	1.0	15.0	1.0	2.0	25.0	4.0%
Great than 1 years and less than and equal to 5 years	2.0	3.0	15.0	4.0	6.0	25.0	12.0%
Greater than 5 years	4.0	6.0	15.0	8.0	12.0	25.0	24.0%
Main index equities (including convertible bonds) and gold				15.0%			
Other publically traded equities (including convertible bonds)				25.0%			
Mutual funds				Highest haircut applicable to any security in which the fund can invest			
Cash collateral				0%			

[1] The market price volatility haircut in Table 1 to § 628.37 are based on 10-day holding period.

[2] Includes a foreign PSE that receives a 0-percent risk weight.

(ii) For currency mismatches, a System institution must use a haircut for foreign exchange rate volatility (H_{fx}) of 8 percent, as adjusted in certain circumstances under paragraphs (c)(3)(iii) and (iv) of this section.

(iii) For repo-style transactions, a System institution may multiply the standard supervisory haircuts provided in paragraphs (c)(3)(i) and (ii) of this section by the square root of ½ (which equals 0.707107).

(iv) If the number of trades in a netting set exceeds 5,000 at any time during a quarter, a System institution must adjust the supervisory haircuts provided in paragraphs (c)(3)(i) and (ii) of this section upward on the basis of a holding period of 20 business days for the following quarter except in the calculation of the exposure amount for purposes of § 628.35. If a netting set contains one or more trades involving illiquid collateral or an OTC derivative that cannot be easily replaced, a System institution must adjust the supervisory haircuts upward on the basis of a holding period of 20 business days. If over the 2 previous quarters more than two margin disputes on a netting set have occurred that lasted more than the holding period, then the System institution must adjust the supervisory haircuts upward for that netting set on the basis of a holding period that is at least two times the minimum holding period for that netting set. A System institution must adjust the standard supervisory haircuts upward using the following formula:

$$H_A = H_S \sqrt{\frac{T_M}{T_S}}$$

Where:

T_M = a holding period of longer than 10 business days for eligible margin loans and derivative contracts or longer than 5 business days for repo-style transactions;

H_S = the standard supervisory haircut; and

T_S = 10 business days for eligible margin loans and derivative contracts or 5 business days for repo-style transactions.

(v) If the instrument a System institution has lent, sold subject to repurchase, or posted as collateral does not meet the definition of financial collateral in § 628.2, the System institution must use a 25-percent haircut for fair value price volatility (H_S).

(4) [Reserved]

Risk-Weighted Assets for Unsettled Transactions

§ 628.38 Unsettled transactions.

(a) *Definitions.* For purposes of this section:

(1) Delivery-versus-payment (DvP) transaction means a securities or commodities transaction in which the buyer is obligated to make payment only if the seller has made delivery of the securities or commodities and the seller is obligated to deliver the securities or commodities only if the buyer has made payment.

(2) Payment-versus-payment (PvP) transaction means a foreign exchange transaction in which each counterparty is obligated to make a final transfer of one or more currencies only if the other counterparty has made a final transfer of one or more currencies.

(3) A transaction has a normal settlement period if the contractual settlement period for the transaction is equal to or less than the fair value standard for the instrument underlying the transaction and equal to or less than 5 business days.

(4) Positive current exposure of a System institution for a transaction is the difference between the transaction value at the agreed settlement price and the current fair value price of the transaction, if the difference results in a credit exposure of the System institution to the counterparty.

(b) *Scope.* This section applies to all transactions involving securities, foreign exchange instruments, and commodities that have a risk of delayed settlement or delivery. This section does not apply to:

(1) Cleared transactions that are marked-to-fair value daily and subject to daily receipt and payment of variation margin;

(2) Repo-style transactions, including unsettled repo-style transactions;

(3) One-way cash payments on OTC derivative contracts; or

(4) Transactions with a contractual settlement period that is longer than the normal settlement period (which are treated as OTC derivative contracts as provided in § 628.34).

(c) *System-wide failures.* In the case of a system-wide failure of a settlement, clearing system or central counterparty, the FCA may waive risk-based capital requirements for unsettled and failed transactions until the situation is rectified.

(d) *Delivery-versus-payment (DvP) and payment-versus-payment (PvP) transactions.* A System institution must hold risk-based capital against any DvP or PvP transaction with a normal settlement period if the System institution's counterparty has not made delivery or payment within 5 business days after the settlement date. The System institution must determine its risk-weighted asset amount for such a transaction by multiplying the positive current exposure of the transaction for the System institution by the appropriate risk weight in Table 1 to § 628.38.

TABLE 1 TO § 628.38—RISK WEIGHTS FOR UNSETTLED DVP AND PVP TRANSACTIONS

Number of business days after contractual settlement date	Risk weight to be applied to positive current exposure (in percent)
From 5 to 15	100.0
From 16 to 30	625.0
From 31 to 45	937.5
46 or more	1,250.0

(e) *Non-DvP/non-PvP (non-delivery-versus-payment/non-payment-versus-payment) transactions.* (1) A System institution must hold risk-based capital against any non-DvP/non-PvP transaction with a normal settlement period if the System institution has delivered cash, securities, commodities, or currencies to its counterparty but has not received its corresponding deliverables by the end of the same business day. The System institution must continue to hold risk-based capital against the transaction until the System institution has received its corresponding deliverables.

(2) From the business day after the System institution has made its delivery until 5 business days after the counterparty delivery is due, the System institution must calculate the risk-weighted asset amount for the transaction by treating the current fair value of the deliverables owed to the System institution as an exposure to the counterparty and using the applicable counterparty risk weight under § 628.32.

(3) If the System institution has not received its deliverables by the 5th business day after counterparty delivery was due, the System institution must assign a 1,250-percent risk weight to the current fair value of the deliverables owed to the System institution.

(f) *Total risk-weighted assets for unsettled transactions.* Total risk-weighted assets for unsettled transactions is the sum of the risk-weighted asset amounts of all DvP, PvP, and non-DvP/non-PvP transactions.

§§ 628.39 through 628.40 [Reserved]

Risk-Weighted Assets for Securitization Exposures

§ 628.41 Operational requirements for securitization exposures.

(a) *Operational criteria for traditional securitizations.* A System institution that transfers exposures it has originated or purchased to a third party in connection with a traditional securitization may exclude the exposures from the calculation of its risk-weighted assets only if each condition in this section is satisfied. A System institution that meets these conditions must hold risk-based capital against any credit risk it retains in connection with the securitization. A System institution that fails to meet these conditions must hold risk-based capital against the transferred exposures as if they had not been securitized and must deduct from CET1 capital, pursuant to § 628.22, any after-tax gain-on-sale resulting from the transaction. The conditions are:

(1) The exposures are not reported on the System institution's consolidated balance sheet under GAAP;

(2) The System institution has transferred to one or more third parties credit risk associated with the underlying exposures;

(3) Any clean-up calls relating to the securitization are eligible clean-up calls; and

(4) The securitization does not:

(i) Include one or more underlying exposures in which the borrower is permitted to vary the drawn amount within an agreed limit under a line of credit; and

(ii) Contain an early amortization provision.

(b) *Operational criteria for synthetic securitizations.* For synthetic securitizations, a System institution may recognize for risk-based capital purposes the use of a credit risk mitigant to hedge underlying exposures only if each condition in this paragraph is satisfied. A System institution that meets these conditions must hold risk-based capital against any credit risk of the exposures it retains in connection with the synthetic securitization. A System institution that fails to meet these conditions or chooses not to recognize the credit risk mitigant for purposes of this section must instead hold risk-based capital against the underlying exposures as if they had not been synthetically securitized. The conditions are:

(1) The credit risk mitigant is:

(i) Financial collateral;

(ii) A guarantee that meets all criteria set forth in the definition of "eligible guarantee" in § 628.2, except for the criteria in paragraph (3) of that definition; or

(iii) A credit derivative that meets all criteria as set forth in the definition of "eligible credit derivative" in § 628.2, except for the criteria in paragraph (3) of the definition of "eligible guarantee" in § 628.2.

(2) The System institution transfers credit risk associated with the underlying exposures to one or more third parties, and the terms and conditions in the credit risk mitigants employed do not include provisions that:

(i) Allow for the termination of the credit protection due to deterioration in the credit quality of the underlying exposures;

(ii) Require the System institution to alter or replace the underlying exposures to improve the credit quality of the pool of underlying exposures;

(iii) Increase the System institution's cost of credit protection in response to deterioration in the credit quality of the underlying exposures;

(iv) Increase the yield payable to parties other than the System institution in response to a deterioration in the credit quality of the underlying exposures; or

(v) Provide for increases in a retained first loss position or credit enhancement provided by the System institution after the inception of the securitization;

(3) The System institution obtains a well-reasoned opinion from legal counsel that confirms the enforceability of the credit risk mitigant in all relevant jurisdictions; and

(4) Any clean-up calls relating to the securitization are eligible clean-up calls.

(c) *Due diligence requirements.* (1) Except for exposures that are deducted from CET1 capital (pursuant to § 628.22) and exposures subject to § 628.42(h), if a System institution is unable to demonstrate to the satisfaction of the FCA a comprehensive understanding of the features of a securitization exposure that would materially affect the performance of the exposure, the System institution must assign the securitization exposure a risk weight of 1,250 percent. The System institution's analysis must be commensurate with the complexity of the securitization exposure and the materiality of the exposure in relation to its capital.

(2) A System institution must demonstrate its comprehensive understanding of a securitization exposure under paragraph (c)(1) of this section for each securitization exposure by:

(i) Conducting an analysis of the risk characteristics of a securitization exposure prior to acquiring the exposure, and documenting such analysis within 3 business days after acquiring the exposure, considering:

(A) Structural features of the securitization that would materially impact the performance of the exposure, for example, the contractual cash flow waterfall, waterfall-related triggers, credit enhancements, liquidity enhancements, fair value triggers, the performance of organizations that service the exposure, and deal-specific definitions of default;

(B) Relevant information regarding the performance of the underlying credit exposure(s), for example, the percentage of loans 30, 60, and 90 days past due; default rates; prepayment rates; loans in foreclosure; property types; occupancy; average credit score or other measures of creditworthiness; average loan-to-value (LTV) ratio; and industry and geographic diversification data on the underlying exposure(s);

(C) Relevant market data of the securitization, for example, bid-ask spread, most recent sales price and historic price volatility, trading volume, implied market rating, and size, depth and concentration level of the market for the securitization; and

(D) For resecuritization exposures, performance information on the underlying securitization exposures, for example, the issuer name and credit quality, and the characteristics and performance of the exposures; and

(ii) On an on-going basis (no less frequently than quarterly), evaluating, reviewing, and updating as appropriate the analysis required under paragraph (c)(1) of this section for each securitization exposure.

§ 628.42 Risk-weighted assets for securitization exposures.

(a) *Securitization risk weight approaches.* Except as provided in this section or in § 628.41:

(1) A System institution must deduct from CET1 capital any after-tax gain-on-sale resulting from a securitization (as provided in § 628.22) and must apply a 1,250-percent risk weight to the portion of a credit-enhancing interest-only strip (CEIO) that does not constitute after-tax gain-on-sale.

(2) If a securitization exposure does not require deduction under paragraph (a)(1) of this section, a System institution may assign a risk weight to the securitization exposure using the simplified supervisory formula approach (SSFA) in accordance with § 628.43(a) through (d) and subject to the limitation under paragraph (e) of this section. Alternatively, a System institution may assign a risk weight to the purchased securitization exposure using the gross-up approach in accordance with § 628.43(e), provided however, that such System institution must apply either the SSFA or the gross-up approach consistently across all of its securitization exposures, except as provided in paragraphs (a)(1), (3), and (4) of this section.

(3) If a securitization exposure does not require deduction under paragraph (a)(1) of this section and the System institution cannot or chooses not to apply the SSFA or the gross-up approach to the exposure, the System institution must assign a risk weight to the exposure as described in § 628.44.

(4) If a securitization exposure is a derivative contract (other than protection provided by a System institution in the form of a credit derivative) that has a first priority claim on the cash flows from the underlying exposures (notwithstanding amounts due under interest rate or currency derivative contracts, fees due, or other similar payments), a System institution may choose to set the risk-weighted asset amount of the exposure equal to the amount of the exposure as determined in paragraph (c) of this section.

(b) *Total risk-weighted assets for securitization exposures.* A System institution's total risk-weighted assets for securitization exposures equals the sum of the risk-weighted asset amount for securitization exposures that the System institution risk weights under paragraph (a)(1) of this section, § 628.41(c), and § 628.43, § 628.44, or § 628.45, except as provided in paragraphs (e) through (j) of this section, as applicable.

(c) *Exposure amount of a securitization exposure.* (1) [Reserved]

(2) *On-balance sheet securitization exposures (available-for-sale or held-to-maturity securities).* The exposure amount of an on-balance sheet securitization exposure that is an available-for-sale or held-to-maturity security is the System institution's carrying value (including net accrued but unpaid interest and fees), less any net unrealized gains on the exposure and plus any net unrealized losses on the exposure.

(3) *Off-balance sheet securitization exposures.* (i) Except as provided in paragraph (j) of this section, the exposure amount of an off-balance sheet securitization that is not a repo-style transaction, an eligible margin loan, a cleared transaction (other than a credit derivative), or an OTC derivative contract (other than a credit derivative) is the notional amount of the exposure.

(ii) [Reserved]

(iii) [Reserved]

(4) *Repo-style transactions, eligible margin loans, and derivative contracts.* The exposure amount of a securitization exposure that is a repo-style transaction, an eligible margin loan, or a derivative contract (other than a credit derivative) is the exposure amount of the transaction as calculated under § 628.34 or § 628.37 as applicable.

(d) *Overlapping exposures.* If a System institution has multiple securitization exposures that provide duplicative coverage to the underlying exposures of a securitization, the System institution is not required to hold duplicative risk-based capital against the overlapping position. Instead, the System institution may apply to the overlapping position the applicable risk-based capital treatment that results in the highest risk-based capital requirement.

(e) *Implicit support.* If a System institution provides support to a securitization in excess of the System institution's contractual obligation to provide credit support to the securitization (implicit support):

(1) The System institution must include in risk-weighted assets all of the underlying exposures associated with the securitization as if the exposures had not been securitized and must deduct from CET1 capital (pursuant to § 628.22) any after-tax gain-on-sale resulting from the securitization; and

(2) The System institution must disclose publicly:

(i) That it has provided implicit support to the securitization; and

(ii) The risk-based capital impact to the System institution of providing such implicit support.

(f) *Undrawn portion of an eligible servicer cash advance facility.* (1) Notwithstanding any other provision of this subpart, a System institution that is a servicer under an eligible servicer cash advance facility is not required to hold risk-based capital against potential future cash advance payments that it may be required to provide under the contract governing the facility.

(2) For a System institution that acts as a servicer, the exposure amount for a servicer cash advance facility that is not an eligible cash advance facility is equal to the amount of all potential future cash payments that the System institution may be contractually required to provide during the subsequent 12-month period under the governing facility.

(g) *Interest-only mortgage-backed securities.* Regardless of any other provisions of this subpart, the risk weight for a non-credit-enhancing interest-only mortgage-backed security may not be less than 100 percent.

(h) Small-business loans and leases on personal property transferred with retained contractual exposure. (1) Regardless of any other provisions of this subpart, a System institution that has transferred small-business loans and leases on personal property (small-business obligations) must include in risk-weighted assets only its contractual exposure to the small-business obligations if all the following conditions are met:

(i) The transaction must be treated as a sale under GAAP.

(ii) The System institution establishes and maintains, pursuant to GAAP, a non-capital reserve sufficient to meet the System institution's reasonably estimated liability under the contractual obligation.

(iii) The small business obligations are to businesses that meet the criteria for a small-business concern established by the Small Business Administration under section 3(a) of the Small Business Act.

(iv) [Reserved]

(2) The total outstanding amount of contractual exposure retained by a System institution on transfers of small-business obligations receiving the capital treatment specified in paragraph (h)(1) of this section cannot exceed 15 percent of the System institution's total capital.

(3) If a System institution exceeds the 15-percent capital limitation provided in paragraph (h)(2) of this section, the capital treatment under paragraph (h)(1) of this section will continue to apply to any transfers of small-business obligations with retained contractual exposure that occurred during the time that the System institution did not exceed the capital limit.

(4) [Reserved]

(i) [Reserved]

(ii) [Reserved]

(i) *Nth-to-default credit derivatives*—(1) *Protection provider.* A System institution must assign a risk weight to an nth-to-default credit derivative in accordance with FCA guidance.

(2) [Reserved]

(3) [Reserved]

(4) *Protection purchaser*—(i) *First-to-default credit derivatives.* A System institution that obtains credit protection on a group of underlying exposures through a first-to-default credit derivative that meets the rules of recognition of § 628.36(b) must determine its risk-based capital requirement for the underlying exposures as if the System institution synthetically securitized the underlying exposure with the smallest risk-weighted asset amount and had obtained no credit risk mitigant on the other underlying exposures. A System institution must calculate a risk-based capital requirement for counterparty credit risk according to § 628.34 for a first-to-default credit derivative that does not meet the rules of recognition of § 628.36(b).

(ii) *Second-or-subsequent-to-default credit derivatives.* (A) A System institution that obtains credit protection on a group of underlying exposures through a nth-to-default credit derivative that meets the rules of recognition of § 628.36(b) (other than a first-to-default credit derivative) may recognize the credit risk mitigation benefits of the derivative only if:

(*1*) The System institution also has obtained credit protection on the same underlying exposures in the form of first-through-(n-1)-to-default credit derivatives; or

(*2*) If n-1 of the underlying exposures have already defaulted.

(B) If a System institution satisfies the requirements of paragraph (i)(4)(ii)(A) of this section, the System institution must determine its risk-based capital requirement for the underlying exposures as if the System institution had only synthetically securitized the underlying exposure with the nth smallest risk-weighted asset amount and had obtained no credit risk mitigant on the underlying exposures.

(C) A System institution must calculate a risk-based capital requirement for counterparty credit risk according to § 628.34 for a nth-to-default credit derivative that does not meet the rules of recognition of § 628.36(b).

(j) *Guarantees and credit derivatives other than nth-to-default credit derivatives*—(1) *Protection provider.* For a guarantee or credit derivative (other than an nth-to-default credit derivative) provided by a System institution that covers the full amount or a pro rata share of a securitization exposure's principal and interest, the System institution must risk weight the guarantee or credit derivative in accordance with FCA guidance.

(2) *Protection purchaser.* (i) A System institution that purchases a guarantee or OTC credit derivative (other than an nth-to-default credit derivative) that is recognized under § 628.45 as a credit risk mitigant (including via collateral recognized under § 628.37) is not required to compute a separate credit risk capital requirement under § 628.31, in accordance with § 628.34(c).

(ii) If a System institution cannot, or chooses not to, recognize a purchased credit derivative as a credit risk mitigant under § 628.45, the System institution must determine the exposure amount of the credit derivative under § 628.34.

(A) If the System institution purchases credit protection from a counterparty that is not a securitization special purpose entity (SPE), the System institution must determine the risk weight for the exposure according to general risk weights under § 628.32.

(B) If the System institution purchases the credit protection from a counterparty that is a securitization SPE, the System institution must determine the risk weight for the exposure according to this section, including paragraph (a)(4) of this section for a credit derivative that has a first priority claim on the cash flows from the underlying exposures of the securitization SPE (notwithstanding amounts due under interest rate or currency derivative contracts, fees due, or other similar payments).

§ 628.43 Simplified supervisory formula approach (SSFA) and the gross-up approach.

(a) *General requirements for the SSFA.* To use the SSFA to determine the risk weight for a securitization exposure, a System institution must have data that enables it to assign accurately the parameters described in paragraph (b) of this section. Data used to assign the parameters described in paragraph (b) of this section must be the most currently available data; if the contract governing the underlying exposures of the securitization require payment on a monthly or quarterly basis, the data used to assign the parameters described in paragraph (b) of this section must be no more than 91 calendar days old. A System institution that does not have the appropriate data to assign the parameters described in paragraph (b) of this section must assign a risk weight of 1,250 percent to the exposure.

(b) *SSFA parameters.* To calculate the risk weight for a securitization exposure using the SSFA, a System institution must have accurate information on the following five inputs to the SSFA calculation:

(1) K_G is the weighted-average (with unpaid principal used as the weight for each exposure) total capital requirement of the underlying exposures calculated using this subpart. K_G is expressed as a decimal value between 0 and 1 (that is, an average risk weight of 100 percent represents a value of K_G equal to .08).

(2) Parameter *W* is expressed as a decimal value between 0 and 1. Parameter *W* is the ratio of the sum of the dollar amounts of any underlying exposures within the securitized pool that meet any of the criteria as set forth in paragraphs (b)(2)(i) through (vi) of this section to the balance, measured in dollars, of underlying exposures:

(i) Ninety (90) days or more past due;

(ii) Subject to a bankruptcy or insolvency proceeding;

(iii) In the process of foreclosure;

(iv) Held as real estate owned;

(v) Has contractually deferred interest payments for 90 days or more, other than principal or interest payments deferred on:

(A) Federally guaranteed student loans, in accordance with the terms of those guarantee programs; or

(B) Consumer loans, including non-federally guaranteed student loans, provided that such payments are deferred pursuant to provisions included in the contract at the time funds are disbursed that provide for periods(s) of deferral that are not initiated based on changes in the creditworthiness of the borrower; or

(vi) Is in default.

(3) Parameter *A* is the attachment point for the exposure, which represents the threshold at which credit losses will first be allocated to the exposure. Except as provided in § 628.42(i) for nth-to-default credit derivatives, parameter *A* equals the ratio of the current dollar amount of underlying exposures that are subordinated to the exposure of the System institution to the current dollar amount of underlying exposures. Any reserve account funded by the accumulated cash flows from the underlying exposures that is subordinated to the System institution's securitization exposure may be included in the calculation of parameter *A* to the extent that cash is present in the account. Parameter *A* is expressed as a decimal value between 0 and 1.

(4) Parameter *D* is the detachment point for the exposure, which represents the threshold at which credit losses of principal allocated to the exposure would result in a total loss of principal. Except as provided in § 628.42(i) for nth-to-default credit derivatives, parameter *D* equals parameter *A* plus the ratio of the current dollar amount of the securitization exposures that are *pari passu* with the exposure (that is, have equal seniority with respect to credit risk) to the current dollar amount of the underlying exposures. Parameter *D* is expressed as a decimal value between 0 and 1.

(5) A supervisory calibration parameter, *p*, is equal to 0.5 for securitization exposures that are not resecuritization exposures and equal to 1.5 for resecuritization exposures.

(c) *Mechanics of the SSFA.* K_G and *W* are used to calculate K_A, the augmented value of K_G, which reflects the observed credit quality of the underlying pool of exposures. K_A is defined in paragraph (d) of this section. The values of parameters *A* and *D*, relative to K_A determine the risk weight assigned to a securitization exposure as described in paragraph (d) of this section. The risk weight assigned to a securitization exposure, or portion of a securitization exposure, as appropriate, is the larger of the risk weight determined in accordance with this paragraph (d) of this section and a risk weight of 20 percent.

(1) When the detachment point, parameter *D*, for a securitization exposure is less than or equal to K_A, the exposure must be assigned a risk weight of 1,250 percent.

(2) When the attachment point, parameter *A*, for a securitization exposure is greater than or equal to K_A, the System institution must calculate the risk weight in accordance with paragraph (d) of this section.

(3) When *A* is less than K_A and *D* is greater than K_A, the risk weight is a weighted average of 1,250 percent and 1,250 percent times K_{SSFA} calculated in accordance with paragraph (d) of this section. For the purpose of this weighted-average calculation:

(i) The weight assigned to 1,250 percent equals:

$$\frac{K_A - A}{D - A}$$

(ii) The weight assigned to 1,250 percent times K_{SSFA} equals:

$$\frac{D - K_A}{D - A}$$

(iii) The risk weight will be set equal to:

$$RW = \left[\left(\frac{K_A - A}{D - A}\right) \times 1,250 \text{ percent}\right] + \left[\left(\frac{D - K_A}{D - A}\right) \times 1,250 \text{ percent} \times K_{SSFA}\right]$$

(d) *SSFA equation.* (1) The System institution must define the following parameters:

$$K_A = (1 - W) \times K_G \times (0.5 \times W)$$

(2) Then the System institution must calculate K_{SSFA} according to the following equation:

$$K_{SSFA}=\frac{e^{au}-e^{al}}{a(u\times l)}$$

Where:

$$a=\frac{1}{p\times K_a},$$

$$u=D-K_A,$$

$$l=\max(A-K_A,0),\text{ and}$$

$$e=2.71828,\text{ the base of the natural logarithm}$$

(3) The risk weight for the exposure (expressed as a percent) is equal to $K_{SSFA} \times 1,250$.

(e) *Gross-up approach*—(1) *Applicability.* A System institution may apply the gross-up approach set forth in this section instead of the SSFA to determine the risk weight of its securitization exposures, provided that it applies the gross-up approach to all of its securitization exposures, except as otherwise provided for certain securitization exposures in §§ 628.44 and 628.45.

(2) To use the gross-up approach, a System institution must calculate the following four inputs:

(i) Pro rata share *A*, which is the par value of the System institution's securitization exposure *X* as a percent of the par value of the tranche in which the securitization exposure resides *Y*:

$$A=\frac{X}{Y}\text{ expressed as a percent}$$

(ii) Enhanced amount *B*, which is the value of tranches that are more senior to the tranche in which the System institution's securitization resides;

(iii) Exposure amount (carrying value) *C* of the System institution's securitization exposure calculated under § 628.42(c); and

(iv) Risk weight (*RW*), which is the weighted-average risk weight of underlying exposures in the securitization pool as calculated under this subpart. For example, *RW* for an asset-backed security with underlying car loans would be 100 percent.

(3) *Credit equivalent amount (CEA).* The CEA of a securitization exposure under this section equals the sum of:

(i) The exposure amount *C* of the System institution's securitization exposure; plus

(ii) The pro rata share *A* multiplied by the enhanced amount *B*, each calculated in accordance with paragraph (e)(2) of this section:

$$CEA = C + (A \times B)$$

(4) *Risk-weighted assets (RWA).* To calculate *RWA* for a securitization exposure under the gross-up approach, a System institution must apply the *RW* calculated under paragraph (e)(2) of this section to the *CEA* calculated in paragraph (e)(3) of this section:

$$RWA = RW \times CEA$$

(f) *Limitations.* Notwithstanding any other provision of this section, a System institution must assign a risk weight of not less than 20 percent to a securitization exposure.

§ 628.44 Securitization exposures to which the SSFA and gross-up approach do not apply.

(a) *General requirement.* A System institution must assign a 1,250-percent risk weight to all securitization exposures to which the System institution does not apply the SSFA or the gross up approach under § 628.43.

(b) [Reserved]

§ 628.45 Recognition of credit risk mitigants for securitization exposures.

(a) *General.* (1) An originating System institution that has obtained a credit risk mitigant to hedge its exposure to a synthetic or traditional securitization that satisfies the operational criteria provided in § 628.41 may recognize the credit risk mitigant under § 628.36 or § 628.37, but only as provided in this section.

(2) An investing System institution that has obtained a credit risk mitigant to hedge a securitization exposure may recognize the credit risk mitigant under § 628.36 or § 628.37, but only as provided in this section.

(b) *Mismatches.* A System institution must make any applicable adjustment to the protection amount of an eligible guarantee or credit derivative as required in § 628.36(d), (e), and (f) for any hedged securitization exposure. In the context of a synthetic securitization, when an eligible guarantee or eligible credit derivative covers multiple hedged exposures that have different residual maturities, the System institution must use the longest residual maturity of any of the hedged exposures as the residual maturity of all hedged exposures.

§§ 628.46 through 628.50 [Reserved]

Risk-Weighted Assets for Equity Exposures

§ 628.51 Introduction and exposure measurement.

(a) *General.* (1) To calculate its risk-weighted asset amounts for equity exposures that are not equity exposures to an investment fund, a System institution must use the Simple Risk-Weight Approach (SRWA) provided in § 628.52. A System institution must use the look-through approaches provided in § 628.53 to calculate its risk-weighted asset amounts for equity exposures to investment funds. Equity investments (including preferred stock investments) in other System institutions, service corporations, and the Funding Corporation do not receive a risk weight, because they are deducted from capital in accordance with § 628.22.

(2) [Reserved]

(3) [Reserved]

(b) *Adjusted carrying value.* For purposes of §§ 628.51 through 628.53, the adjusted carrying value of an equity exposure is:

(1) For the on-balance sheet component of an equity exposure (other than an equity exposure that is classified as available-for-sale), the System institution's carrying value of the exposure;

(2) For the on-balance sheet component of an equity exposure that is classified as available-for-sale, the System institution's carrying value of the exposure less any net unrealized gains on the exposure that are reflected in such carrying value but excluded from the System institution's regulatory capital components;

(3) For the off-balance sheet component of an equity exposure that is not an equity commitment, the effective notional principal amount of the exposure, the size of which is equivalent to a hypothetical on-balance sheet position in the underlying equity instrument that would evidence the same change in fair value (measured in dollars) given a small change in the price of the underlying equity instrument, minus the adjusted carrying value of the on-balance sheet component of the exposure as calculated in paragraph (b)(1) of this section; and

(4) For a commitment to acquire an equity exposure (an equity commitment), the effective notional principal amount of the exposure is multiplied by the following conversion factors (CFs):

(i) Conditional equity commitments with an original maturity of 14 months or less receive a CF of 20 percent.

(ii) Conditional equity commitments with an original maturity of over 14 months receive a CF of 50 percent.

(iii) Unconditional equity commitments receive a CF of 100 percent.

§ 628.52 Simple risk-weight approach (SRWA).

(a) *General.* Under the SRWA, a System institution's total risk-weighted assets for equity exposures equals the sum of the risk-weighted asset amounts for each of the System institution's individual equity exposures (other than equity exposures to an investment fund) as determined under this section and the risk-weighted asset amounts for each of the System institution's individual equity exposures to an investment fund as determined under § 628.53.

(b) *SRWA computation for individual equity exposures.* A System institution must determine the risk-weighted asset amount for an individual equity exposure (other than an equity exposure to an investment fund) by multiplying the adjusted carrying value of the equity exposure or the effective portion and ineffective portion of a hedge pair (as defined in paragraph (c) of this section) by the lowest applicable risk weight in this paragraph.

(1) *Zero-percent (0%) risk weight equity exposures.* An equity exposure to a sovereign, the Bank for International Settlements, the European Central Bank, the European Commission, the International Monetary Fund, an MDB, and any other entity whose credit exposures receive a 0-percent risk weight under § 628.32 may be assigned a 0-percent risk weight.

(2) *Twenty-percent (20%) risk weight equity exposures.* An equity exposure to a PSE or the Federal Agricultural Mortgage Corporation (Farmer Mac) must be assigned a 20-percent risk weight.

(3) *One hundred-percent (100%) risk weight equity exposures.* The equity exposures set forth in this paragraph (b)(3) must be assigned a 100-percent risk weight:

(i) [Reserved]

(ii) *Effective portion of hedge pairs.* The effective portion of a hedge pair.

(iii) *Non-significant equity exposures.* Equity exposures, excluding exposures to an investment firm that would meet the definition of a traditional securitization in § 628.2 were it not for the application of paragraph (8) of that definition and has greater than immaterial leverage, to the extent that aggregate adjusted carrying value of the exposures does not exceed 10 percent of the System institution's total capital.

(A) Equity exposures subject to paragraph (b)(3)(iii) of this section include:

(*1*) Equity exposures to unconsolidated unincorporated business entities and equity exposures held through consolidated unincorporated business entities, as authorized by subpart J of part 611 of this chapter; and

(*2*) [Reserved]

(*3*) Equity exposures to an unconsolidated rural business investment company and equity exposures held through a consolidated rural business investment company described in 7 U.S.C. 2009cc *et seq.*

(B) To compute the aggregate adjusted carrying value of a System institution's equity exposures for purposes of this section, the System institution may exclude equity exposures described in paragraphs (b)(1) and (2) and (b)(3)(ii) of this section, the equity exposure in a hedge pair with the smaller adjusted carrying value, and a proportion of each equity exposure to an investment fund equal to the proportion of the assets of the investment fund that are not equity exposures or that meet the criterion of paragraph (b)(3)(i) of this section. If a System institution does not know the actual holdings of the investment fund, the System institution may calculate the proportion of the assets of the fund that are not equity exposures based on the terms of the prospectus, partnership agreement, or similar contract that defines the fund's permissible investments. If the sum of the investment limits for all exposure classes within the fund exceeds 100 percent, the System institution must assume for purposes of this section that the investment fund invests to the maximum extent possible in equity exposures.

(C) When determining which of a System institution's equity exposures qualify for a 100-percent risk weight under this paragraph, a System institution first must include equity exposures to unconsolidated rural business investment companies or held through consolidated rural business investment companies described in 7 U.S.C. 2009cc *et seq.*; then must include equity exposures to unconsolidated unincorporated business entities and equity exposures held through consolidated unincorporated business entities, as authorized by subpart J of part 611 of this chapter; then must include publicly traded equity exposures (including those held indirectly through investment funds); and then must include non-publicly traded equity exposures (including those held indirectly through investment funds).

(4) *Other equity exposures.* The risk weight for any equity exposure that does not qualify for a risk weight under paragraph (b)(1), (2), (3), or (7) of this section will be determined by the FCA.

(5) [Reserved]

(6) [Reserved]

(7) *Six hundred-percent (600%) risk weight equity exposures.* An equity exposure to an investment firm must be assigned a 600-percent risk weight, provided that the investment firm:

(i) Would meet the definition of a traditional securitization in § 628.2 were it not for the application of paragraph (8) of that definition; and

(ii) Has greater than immaterial leverage.

(c) *Hedge transactions*—(1) *Hedge pair.* A hedge pair is two equity exposures that form an effective hedge so long as each equity exposure is publicly traded or has a return that is primarily based on a publicly traded equity exposure.

(2) *Effective hedge.* Two equity exposures form an effective hedge if the exposures either have the same remaining maturity or each has a remaining maturity of at least 3 months; the hedge relationship is formally documented in a prospective manner (that is, before the System institution acquires at least one of the equity exposures); the documentation specifies the measure of effectiveness (E) the System institution will use for the hedge relationship throughout the life of the transaction; and the hedge relationship has an E greater than or equal to 0.8. A System institution must measure E at least quarterly and must use one of three alternative measures of E as set forth in this paragraph (c):

(i) Under the dollar-offset method of measuring effectiveness, the System institution must determine the ratio of value change (RVC). The RVC is the ratio of the cumulative sum of the changes in value of one equity exposure to the cumulative sum of the changes in the value of the other equity exposure. If RVC is positive, the hedge is not effective and E equals 0. If RVC is negative and greater than or equal to -1 (that is, less than 0 and greater than or equal to -1), then E equals the absolute value of RVC. If RVC is negative and less than -1, then E equals 2 plus RVC.

(ii) Under the variability-reduction method of measuring effectiveness:

$$E = 1 - \frac{\sum_{t=1}^{T}\left(X_t - X_{t-1}\right)^2}{\sum_{t=1}^{T}\left(A_t - A_{t-1}\right)^2}$$

Where:

$X_t = A_t \times B_t$;

A_t = the value at time t of one exposure in a hedge pair; and

Bt = the value at time t of the other exposure in a hedge pair.

(iii) Under the regression method of measuring effectiveness, E equals the coefficient of determination of a regression in which the change in value of one exposure in a hedge pair is the dependent variable and the change in value of the other exposure in a hedge pair is the independent variable. However, if the estimated regression coefficient is positive, then E equals 0.

(3) The effective portion of a hedge pair is E multiplied by the greater of the adjusted carrying values of the equity exposures forming a hedge pair.

(4) The ineffective portion of a hedge pair is (1–E) multiplied by the greater of the adjusted carrying values of the equity exposures forming a hedge pair.

§ 628.53 Equity exposures to investment funds.

(a) *Available approaches.* (1) A System institution must determine the risk-weighted asset amount of an equity exposure to an investment fund under the full look-through approach described in paragraph (b) of this section, the simple modified look-through approach described in paragraph (c) of this section, or the alterative modified look-through approach described paragraph (d) of this section, provided, however, that the minimum risk weight that may be assigned to an equity exposure under this section is 20 percent.

(2) [Reserved]

(3) If an equity exposure to an investment fund is part of a hedge pair and the System institution does not use the full look-through approach, the System institution must use the ineffective portion of the hedge pair as determined under § 628.52(c) as the adjusted carrying value for the equity exposure to the investment fund. The risk-weighted asset amount of the effective portion of the hedge pair is equal to its adjusted carrying value.

(b) *Full look-through approach.* A System institution that is able to calculate a risk-weighted asset amount for its proportional ownership share of each exposure held by the investment fund (as calculated under this subpart as if the proportional ownership share of the adjusted carrying value of each exposure were held directly by the System institution) may set the risk-weighted asset amount of the System institution's exposure to the fund equal to the product of:

(1) The aggregate risk-weighted asset amounts of the exposures held by the fund as if they were held directly by the System institution; and

(2) The System institution's proportional ownership share of the fund.

(c) *Simple modified look-through approach.* Under the simple modified look-through approach, the risk-weighted asset amount for a System institution's equity exposure to an investment fund equals the adjusted carrying value of the equity exposure multiplied by the highest risk weight that applies to any exposure the fund is permitted to hold under the prospectus, partnership agreement, or similar agreement that defines the fund's permissible investments (excluding derivative contracts that are used for hedging rather than speculative purposes and that do not constitute a material portion of the fund's exposures).

(d) *Alternative modified look-through approach.* Under the alternative modified look-through approach, a System institution may assign the adjusted carrying value of an equity exposure to an investment fund on a pro rata basis to different risk weight categories under this subpart based on the investment limits in the fund's prospectus, partnership agreement, or similar contract that defines the fund's permissible investments. The risk-weighted asset amount for the System institution's equity exposure to the investment fund equals the sum of each portion of the adjusted carrying value assigned to an exposure type multiplied by the applicable risk weight under this subpart. If the sum of the investment limits for all exposure types within the fund exceeds 100 percent, the System institution must assume that the fund invests to the maximum extent permitted under its investment limits in the exposure type with the highest applicable risk weight under this subpart and continues to make investments in order of the exposure type with the next highest applicable risk weight under this subpart until the maximum total investment level is reached. If more than one exposure type applies to an exposure, the System institution must use the highest applicable risk weight. A System institution may exclude derivative contracts held by the fund that are used for hedging rather than for speculative purposes and do not constitute a material portion of the fund's exposures.

§§ 628.54 through 628.60 [Reserved]

Disclosures

§ 628.61 Purpose and scope.

Sections 628.62 and 628.63 establish public disclosure requirements for each System bank related to the capital requirements contained in this part.

§ 628.62 Disclosure requirements.

(a) A System bank must provide timely public disclosures each calendar quarter of the information in the applicable tables in § 628.63. The System bank must make these disclosures in its quarterly and annual reports to shareholders required in part 620 of this chapter. The System bank need not make these disclosures in the format set out in the applicable tables or all in the same location in a report, as long as a summary table specifically indicating the location(s) of all such disclosures is provided. If a significant change occurs, such that the most recent reported amounts are no longer reflective of the System bank's capital adequacy and risk profile, then a brief discussion of this change and its likely impact must be disclosed as soon as practicable thereafter. This disclosure requirement may be satisfied by providing a notice under § 620.15 of this chapter. Qualitative disclosures that typically do not change each quarter (for example, a general summary of the System bank's risk management objectives and policies, reporting system, and definitions) may be disclosed annually after the end of the 4th calendar quarter, provided that any significant changes are disclosed in the interim.

(b) A System bank must have a formal disclosure policy approved by the board of directors that addresses its approach for determining the disclosures it makes. The policy must address the associated internal controls and disclosure controls and procedures. The board of directors and senior management are responsible for establishing and maintaining an effective internal control structure over financial reporting, including the disclosures required by this subpart, and must ensure that appropriate review of the disclosures takes place. The chief executive officer, the chief financial officer, and a designated board member must attest that the disclosures meet the requirements of this subpart.

(c) If a System bank concludes that disclosure of specific proprietary or confidential commercial or financial information that it would otherwise be required to disclose under this section would compromise its position, then the System bank is not required to disclose that specific information pursuant to this section, but must disclose more general information about the subject matter of the requirement, together with the fact that, and the reason why, the specific items of information have not been disclosed.

§ 628.63 Disclosures.

(a) Except as provided in § 628.62, a System bank must make the disclosures described in Tables 1 through 10 of this section. The System bank must make these disclosures publicly available for each of the last 3 years (that is, 12 quarters) or such shorter period beginning on January 1, 2017.

(b) A System bank must publicly disclose each quarter the following:

(1) CET1 capital, tier 1 capital, and total capital ratios, including all the regulatory capital elements and all the regulatory adjustments and deductions needed to calculate the numerator of such ratios;

(2) Total risk-weighted assets, including the different regulatory adjustments and deductions needed to calculate total risk-weighted assets;

(3) Regulatory capital ratios during the transition period, including a description of all the regulatory capital elements and all regulatory adjustments and deductions needed to calculate the numerator and denominator of each capital ratio during the transition period; and

(4) A reconciliation of regulatory capital elements as they relate to its balance sheet in any audited consolidated financial statements.

TABLE 1 TO § 628.63—SCOPE OF APPLICATION

Qualitative Disclosures	(a) The name of the top corporate entity in the group to which this subpart applies.[1] (b) A brief description of the differences in the basis for consolidating entities[2] for accounting and regulatory purposes, with a description of those entities: (1) That are fully consolidated; (2) That are deconsolidated and deducted from total capital; (3) For which the total capital requirement is deducted; and (4) That are neither consolidated nor deducted (for example, where the investment in the entity is assigned a risk weight in accordance with this subpart). (c) Any restrictions, or other major impediments, on transfer of funds or total capital within the group.
Quantitative Disclosures	(d) [Reserved] (e) The aggregate amount by which actual total capital is less than the minimum total capital requirement in all subsidiaries, with total capital requirements and the name(s) of the subsidiaries with such deficiencies.

[1] The System bank is the top corporate entity.

[2] Entities include any subsidiaries authorized by the FCA, including operating subsidiaries, service corporations, and unincorporated business entities.

TABLE 2 TO § 628.63—CAPITAL STRUCTURE

Qualitative Disclosures	(a) Summary information on the terms and conditions of the main features of all regulatory capital instruments.
Quantitative Disclosures	(b) The amount of common equity tier 1 capital, with separate disclosure of: (1) Common cooperative equities a. Statutory minimum purchased borrower stock; b. Other required member purchased stock; c. Allocated equities (stock or surplus): 1. Qualified allocated equities subject to retirement; 2. Nonqualified allocated equities subject to retirement; 3. Nonqualified allocated equities not subject to retirement; (2) Unallocated retained earnings (URE);

TABLE 2 TO § 628.63—CAPITAL STRUCTURE—Continued

	(3) Paid-in capital; and (4) Regulatory adjustments and deductions made to common equity tier 1 capital. (c) The amount of tier 1 capital, with separate disclosure of: (1) Additional tier 1 capital elements; and (2) Regulatory adjustments and deductions made to tier 1 capital. (d) The amount of total capital, with separate disclosure of: (1) Common cooperative equities not included in common equity tier 1 capital; (2) Tier 2 capital elements, including tier 2 capital instruments; and (3) Regulatory adjustments and deductions made to total capital, including deductions of third-party capital under § 628.23.

TABLE 3 TO § 628.63—CAPITAL ADEQUACY

Qualitative disclosures	(a) A summary discussion of the System bank's approach to assessing the adequacy of its capital to support current and future activities.
Quantitative disclosures	(b) Risk-weighted assets for: (1) Exposures to sovereign entities; (2) Exposures to certain supranational entities and MDBs; (3) Exposures to GSEs; (4) Exposures to depository institutions, foreign banks, and credit unions, including OFI exposures that are risk weighted as exposures to U.S. depository institutions and credit unions; (5) Exposures to PSEs; (6) Corporate exposures, including borrower loans (including agricultural and consumer loans) and OFI exposures that are not risk weighted as exposures to U.S. depository institutions and credit unions; (7) Residential mortgage exposures; (8) [Reserved] (9) Past due and nonaccrual exposures; (10) Exposures to other assets; (11) Cleared transactions; (12) Unsettled transactions; (13) Securitization exposures; and (14) Equity exposures. (c) [Reserved] (d) Common equity tier 1, tier 1 and total risk-based capital ratios for the System bank. (e) Total standardized risk-weighted assets.

TABLE 4 TO § 628.63—CAPITAL BUFFERS

Quantitative Disclosures	(a) At least quarterly, the System bank must calculate and publicly disclose the capital conservation buffer and leverage buffer as described under § 628.11. (b) At least quarterly, the System bank must calculate and publicly disclose the eligible retained income of the System bank, as described under § 628.11. (c) At least quarterly, the System bank must calculate and publicly disclose any limitations it has on distributions and discretionary bonus payments resulting from the buffer framework described under § 628.11, including the maximum payout amount and/or maximum leverage payout amount for the quarter.

(c) *General qualitative disclosure requirement.* For each separate risk area described in Tables 5 through 10 of this section, the System bank must describe its risk management objectives and policies, including: Strategies and processes; the structure and organization of the relevant risk management function; the scope and nature of risk reporting and/or measurement systems; policies for hedging and/or mitigating risk and strategies and processes for monitoring the continuing effectiveness of hedges/mitigants.

TABLE 5 TO § 628.63 [1]—CREDIT RISK: GENERAL DISCLOSURES

Qualitative Disclosures	(a) The general qualitative disclosure requirement with respect to credit risk (excluding counterparty credit risk disclosed in accordance with Table 6 of this section), including the: (1) Policy for determining past due or delinquency status; (2) Policy for placing loans in nonaccrual status; (3) Policy for returning loans to accrual status; (4) Definition of and policy for identifying impaired loans (for financial accounting purposes); (5) Description of the methodology that the System bank uses to estimate its allowance for loan losses, including statistical methods used where applicable; (6) Policy for charging-off uncollectible amounts; and (7) Discussion of the System bank's credit risk management policy.

TABLE 5 TO § 628.63[1]—CREDIT RISK: GENERAL DISCLOSURES—Continued

Quantitative Disclosures	(b) Total credit risk exposures and average credit risk exposures, after accounting offsets in accordance with GAAP, without taking into account the effects of credit risk mitigation techniques (for example, collateral and netting not permitted under GAAP), over the period categorized by major types of credit exposure. For example, System banks could use categories similar to that used for financial statement purposes. Such categories might include, for instance: (1) Loans, off-balance sheet commitments, and other non-derivative off-balance sheet exposures; (2) Debt securities; and (3) OTC derivatives.[2] (c) Geographic distribution of exposures, categorized in significant areas by major types of credit exposure.[3] (d) Industry or counterparty type distribution of exposures, categorized by major types of credit exposure. (e) By major industry or counterparty type: (1) Amount of impaired loans for which there was a related allowance under GAAP; (2) Amount of impaired loans for which there was no related allowance under GAAP; (3) Amount of loans past due 90 days and in nonaccrual status; (4) Amount of loans past due 90 days and still accruing;[4] (5) The balance in the allowance for loan losses at the end of each period according to GAAP; and (6) Charge-offs during the period. (f) Amount of impaired loans and, if available, the amount of past due loans categorized by significant geographic areas including, if practical, the amounts of allowances related to each geographical area,[5] further categorized as required by GAAP. (g) Reconciliation of changes in allowances for loan losses.[6] (h) Remaining contractual maturity delineation (for example, one year or less) of the whole portfolio, categorized by credit exposure.

[1] This Table 5 does not cover equity exposures, which should be reported in Table 9 of this section.

[2] *See*, for example, ASC Topic 815–10 and 210, as they may be amended from time to time.

[3] A System bank can satisfy this requirement by describing the geographic distribution of its loan portfolio by State or other significant geographic division, if any.

[4] A System bank is encouraged also to provide an analysis of the aging of past-due loans.

[5] The portion of the general allowance that is not allocated to a geographical area should be disclosed separately.

[6] The reconciliation should include the following: A description of the allowance; the opening balance of the allowance; charge-offs taken against the allowance during the period; amounts provided (or reversed) for estimated probable loan losses during the period; any other adjustments (for example, exchange rate differences, business combinations, acquisitions and disposals of subsidiaries), including transfers between allowances; and the closing balance of the allowance. Charge-offs and recoveries that have been recorded directly to the income statement should be disclosed separately.

TABLE 6 TO § 628.63—GENERAL DISCLOSURE FOR COUNTERPARTY CREDIT RISK-RELATED EXPOSURES

Qualitative Disclosures	(a) The general qualitative disclosure requirement with respect to OTC derivatives, eligible margin loans, and repo-style transactions, including a discussion of: (1) The methodology used to assign credit limits for counterparty credit exposures; Policies for securing collateral, valuing and managing collateral, and establishing credit reserves; (3) The primary types of collateral taken; and (4) The impact of the amount of collateral the System bank would have to provide given deterioration in the System bank's own creditworthiness.
Quantitative Disclosures	(b) Gross positive fair value of contracts, collateral held (including type, for example, cash, government securities), and net unsecured credit exposure.[1] A System bank also must disclose the notional value of credit derivative hedges purchased for counterparty credit risk protection and the distribution of current credit exposure by exposure type.[2] (c) Notional amount of purchased credit derivatives used for the System bank's own credit portfolio.

[1] Net unsecured credit exposure is the credit exposure after considering both the benefits from legally enforceable netting agreements and collateral arrangements without taking into account haircuts for price volatility, liquidity, etc.

[2] This may include interest rate derivative contracts, foreign exchange derivative contracts, equity derivative contracts, credit derivatives, commodity or other derivative contracts, repo-style transactions, and eligible margin loans.

TABLE 7 TO § 628.63—CREDIT RISK MITIGATION[1][2]

Qualitative Disclosures	(a) The general qualitative disclosure requirement with respect to credit risk mitigation, including: (1) Policies and processes for collateral valuation and management; (2) A description of the main types of collateral taken by the System bank; (3) The main types of guarantors/credit derivative counterparties and their creditworthiness; and (4) Information about (market or credit) risk concentrations with respect to credit risk mitigation.
Quantitative Disclosures	(b) For each separately disclosed credit risk portfolio, the total exposure that is covered by eligible financial collateral, and after the application of haircuts. (c) For each separately disclosed portfolio, the total exposure that is covered by guarantees/credit derivatives and the risk-weighted asset amount associated with that exposure.

[1] At a minimum, a System bank must provide the disclosures in this Table 7 in relation to credit risk mitigation that has been recognized for the purposes of reducing capital requirements under this subpart. Where relevant, System banks are encouraged to give further information about mitigants that have not been recognized for that purpose.

[2] Credit derivatives that are treated, for the purposes of this subpart, as synthetic securitization exposures should be excluded from the credit risk mitigation disclosures and included within those relating to securitization (Table 8 of this section).

TABLE 8 TO § 628.63—SECURITIZATION [1]

Qualitative Disclosures	(a) The general qualitative disclosure requirement with respect to a securitization (including synthetic securitizations), including a discussion of: (1) The System bank's objectives for securitizing assets, including the extent to which these activities transfer credit risk of the underlying exposures away from the System bank to other entities and including the type of risks assumed and retained with resecuritization activity; [2] (2) The nature of the risks (*e.g.* liquidity risk) inherent in the securitized assets; (3) The roles played by the System bank in the securitization process [3] and an indication of the extent of the System bank's involvement in each of them; (4) The processes in place to monitor changes in the credit and market risk of securitization exposures including how those processes differ for resecuritization exposures; (5) The System bank's policy for mitigating the credit risk retained through securitization and resecuritization exposures; and (6) The risk-based capital approaches that the System bank follows for its securitization exposures including the type of securitization exposure to which each approach applies.
	(b) [Reserved]
	(c) Summary of the System bank's accounting policies for securitization activities, including: (1) Whether the transactions are treated as sales or financings; (2) Recognition of gain-on-sale; (3) Methods and key assumptions applied in valuing retained or purchased interests; (4) Changes in methods and key assumptions from the previous period for valuing retained interests and impact of the changes; (5) Treatment of synthetic securitizations; (6) How exposures intended to be securitized are valued and whether they are recorded under subpart D of this part; and (7) Policies for recognizing liabilities on the balance sheet for arrangements that could require the System bank to provide financial support for securitized assets.
	(d) An explanation of significant changes to any quantitative information since the last reporting period.
Quantitative Disclosures	(e) The total outstanding exposures securitized by the System bank in securitizations that meet the operational criteria provided in § 628.41 (categorized into traditional and synthetic securitizations), by exposure type.[4]
	(f) For exposures securitized by the System bank in securitizations that meet the operational criteria in § 628.41: (1) Amount of securitized assets that are impaired/past due categorized by exposure type; [5] and (2) Losses recognized by the System bank during the current period categorized by exposure type.[6]
	(g) The total amount of outstanding exposures intended to be securitized categorized by exposure type.
	(h) Aggregate amount of: (1) On-balance sheet securitization exposures retained or purchased categorized by exposure type; and (2) Off-balance sheet securitization exposures categorized by exposure type.
	(i) (1) Aggregate amount of securitization exposures retained or purchased and the associated capital requirements for these exposures, categorized between securitization and resecuritization exposures, further categorized into a meaningful number of risk weight bands and by risk-based capital approach (*e.g.,* SSFA); and (2) Exposures that have been deducted entirely from tier 1 capital, CEIOs deducted from total capital (as described in § 628.42(a)(1)), and other exposures deducted from total capital should be disclosed separately by exposure type.
	(j) Summary of current year's securitization activity, including the amount of exposures securitized (by exposure type), and recognized gain or loss on sale by exposure type.
	(k) Aggregate amount of resecuritization exposures retained or purchased categorized according to: (1) Exposures to which credit risk mitigation is applied and those not applied; and (2) Exposures to guarantors categorized according to guarantor creditworthiness categories or guarantor name.

[1] A System bank is not authorized to perform every role in a securitization, and nothing in these capital rules authorizes a System bank to engage in activities relating to securitizations that are not otherwise authorized.

[2] The System bank should describe the structure of resecuritizations in which it participates; this description should be provided for the main categories of resecuritization products in which the System bank is active.

[3] Roles in securitizations generally could include originator, investor, servicer, provider of credit enhancement, sponsor, liquidity provider, or swap provider. As noted in footnote 1 of this table, however, a System bank is not authorized to perform all of these roles.

[4] "Exposures securitized" include underlying exposures originated by the System bank, whether generated by them or purchased, and recognized in the balance sheet, from third parties, and third-party exposures included in sponsored transactions. Securitization transactions (including underlying exposures originally on the System bank's balance sheet and underlying exposures acquired by the System bank from third-party entities) in which the originating System bank (as an originating System institution) does not retain any securitization exposure should be shown separately but need only be reported for the year of inception. System banks are required to disclose exposures regardless of whether there is a capital charge under this part.

[5] Include credit-related other than temporary impairment (OTTI).

[6] For example, charge-offs/allowances (if the assets remain on the System bank's balance sheet) or credit-related OTTI of interest-only strips and other retained residual interests, as well as recognition of liabilities for probable future financial support required of the System bank with respect to securitized assets.

TABLE 9 TO § 628.63—EQUITIES

Qualitative Disclosures	(a) The general qualitative disclosure requirement with respect to equity risk: (1) Differentiation between holdings on which capital gains are expected and those taken under other objectives including for relationship and strategic reasons; and (2) Discussion of important policies covering the valuation of and accounting for equity. This includes the accounting techniques and valuation methodologies used, including key assumptions and practices affecting valuation as well as significant changes in these practices.
Quantitative Disclosures	(b) Value disclosed on the balance sheet of investments, as well as the fair value of those investments; for securities that are publicly traded, a comparison to publicly quoted share values where the share price is materially different from fair value. (c) The types and nature of investments, including the amount that is: (1) Publicly traded; and (2) Non-publicly traded. (d) The cumulative realized gains (losses) arising from sales and liquidations in the reporting period. (e) (1) Total unrealized gains (losses).[1] (2) Total latent revaluation gains (losses).[2] (3) Any amounts of the above included in tier 1 or tier 2 capital. (f) [Reserved]

[1] Unrealized gains (losses) recognized on the balance sheet but not through earnings.

[2] Unrealized gains (losses) not recognized either on the balance sheet or through earnings.

TABLE 10 TO § 628.63—INTEREST RATE RISK FOR NON-TRADING ACTIVITIES

Qualitative disclosures	(a) The general qualitative disclosure requirement, including the nature of interest rate risk for non-trading activities and key assumptions, including assumptions regarding loan prepayments and behavior of non-maturity deposits, and frequency of measurement of interest rate risk for non-trading activities.
Quantitative disclosures	(b) The increase (decline) in earnings or economic value (or market value of equity or other relevant measure used by management) for upward and downward rate shocks according to management's method for measuring interest rate risk for non-trading activities, categorized by currency (as appropriate).

§§ 628.64 through 628.99 [Reserved]

Subpart E—[Reserved]

Subpart F—[Reserved]

Subpart G—Transition Provisions

§ 628.300 Transitions.

(a) *Capital conservation buffer.* (1) [Reserved]

(2) Beginning January 1, 2017 through December 31, 2019 a System institution's maximum capital conservation buffer payout ratio must be determined as set forth in Table 1 to § 628.300.

TABLE 1 TO § 628.300

Transition Period	Capital conservation buffer	Maximum payout ratio (as a percentage of eligible retained income)
Calendar year 2017	>0.625 percent	No limitation.
	≤0.625 percent, and >0.469 percent	60 percent.
	≤0.469 percent, and >0.313 percent	40 percent.
	≤0.313 percent, and >0.156 percent	20 percent.
	≤0.156 percent	0 percent.
Calendar year 2018	>1.25 percent	No limitation.
	≤1.25 percent, and >0.938 percent	60 percent.
	≤0.938 percent, and >0.625 percent	40 percent.
	≤0.625 percent, and >0.313 percent	20 percent.
	≤0.313 percent	0 percent.
Calendar year 2019	>1.875 percent	No limitation.
	≤1.875 percent, and >1.406 percent	60 percent.
	≤1.406 percent, and >0.938 percent	40 percent.
	≤0.938 percent, and >0.469 percent	20 percent.
	≤0.469 percent	0 percent.

(b) through (e) [Reserved]

§ 628.301 Initial compliance and reporting requirements.

(a) A System institution that fails to satisfy one or more of its minimum applicable CET1, tier 1, or total risk-based capital ratios or its tier 1 leverage ratio at the end of the quarter in which these regulations become effective shall report its initial noncompliance to the FCA within 20 days following such quarterend and shall also submit a capital restoration plan for achieving and maintaining the standards, demonstrating appropriate annual progress toward meeting the goal, to the FCA within 60 days following such quarterend. If the capital restoration plan is not approved by the FCA, the FCA will inform the institution of the reasons for disapproval, and the institution shall submit a revised capital restoration plan within the time specified by the FCA.

(b) *Approval of compliance plans.* In determining whether to approve a capital restoration plan submitted under this section, the FCA shall consider the following factors, as applicable:

(1) The conditions or circumstances leading to the institution's falling below minimum levels, the exigency of those circumstances, and whether or not they were caused by actions of the institution or were beyond the institution's control;

(2) The overall condition, management strength, and future prospects of the institution and, if applicable, affiliated System institutions;

(3) The institution's capital, adverse assets (including nonaccrual and nonperforming loans), ALL, and other ratios compared to the ratios of its peers or industry norms;

(4) How far an institution's ratios are below the minimum requirements;

(5) The estimated rate at which the institution can reasonably be expected to generate additional earnings;

(6) The effect of the business changes required to increase capital;

(7) The institution's previous compliance practices, as appropriate;

(8) The views of the institution's directors and senior management regarding the plan; and

(9) Any other facts or circumstances that the FCA deems relevant.

(c) An institution shall be deemed to be in compliance with the regulatory capital requirements of this subpart if it is in compliance with a capital restoration plan that is approved by the FCA within 180 days following the end of the quarter in which these regulations become effective.

Dated: May 17, 2016.

Dale L. Aultman,

Secretary, Farm Credit Administration Board.

[FR Doc. 2016–12072 Filed 7–27–16; 8:45 am]

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Part III

Department of Justice

Drug Enforcement Administration

Hills Pharmacy, LLC; Decision and Order; Notices

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 15–4]

Hills Pharmacy, LLC; Decision and Order

On October 8, 2014, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Hills Pharmacy, LLC (hereinafter, Hills or Respondent), which proposed the revocation of its DEA Certificate of Registration FH0772257, pursuant to which it is authorized to dispense controlled substances in schedules II through V as a retail pharmacy, at the registered location of 7730 W. Hillsborough Ave., Tampa, Florida. ALJ Ex. 1, at 1. As grounds for the proposed action (which also includes the denial of any pending applications), the Show Cause Order alleged that Respondent's "continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f)." *Id.; see also* 21 U.S.C. 824(a)(4).

More specifically, the Show Cause Order alleged that Respondent's "pharmacists repeatedly failed to exercise their corresponding responsibility to ensure that controlled substances they dispensed were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting within the usual course of their professional practice" and that its "pharmacists ignored readily identifiable red flags that [the] controlled substances prescribed were being diverted and dispensed despite unresolved red flags." *Id.* (citing 21 CFR 1306.04(a); *Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195,* 77 FR 62315, 62319 (2012)). The Show Cause Order further alleged that Respondent's "pharmacists dispensed controlled substances when they knew or should have known that the prescriptions were not issued in the usual course of professional practice or for a legitimate medical purpose, including circumstances where the pharmacist knew or should have known that the controlled substances were abused and/or diverted by the customer." *Id.* at 2.

The Show Cause Order listed various red flags which Respondent's pharmacists allegedly failed to resolve before dispensing prescriptions, including: (1) "multiple individuals presenting prescriptions for the same drugs in the same quantities from the same doctor"; (2) "individuals presenting prescriptions for controlled substances known to be highly abused, such as oxycodone and hydromorphone"; (3) "individuals paying high prices . . . for controlled substances with cash"; and (4) "individuals residing long distances from the pharmacy." *Id.*

The Show Cause Order then alleged that between July 28 and August 4, 2011, Respondent's "pharmacists dispensed large and substantially similar quantities of" oxycodone 30 mg tablets "to at least nine customers, all of whom received their prescriptions from physicians working at the same clinic," and that seven of the customers "resided at least [50] miles from" Respondent and five of the customers "resided more than [100] miles from" it. *Id.* The Government specifically alleged that "on July 28, 2011, a Hills . . . pharmacist dispensed 210" tablets of oxycodone 30 mg "to T.V., who resided in Pensacola, . . . more than [450] miles from" Respondent. The Order also alleged that "on August 4, 2011, one or more Hills . . . pharmacists dispensed large quantities of oxycodone pursuant to prescriptions written by the same physician on the same day to two customers with the same last name" (J.P. and T.P.), both of whom "resided in St., Augustine, Florida, more than [180] miles from" it. *Id.*

Next, the Show Cause Order alleged that "[o]n April 21, 2011, one or more Hills['] . . . pharmacists dispensed large and substantially similar quantities of . . . oxycodone 30 to at least [12] customers, three of whom resided more than [50] miles from [it], and two of whom resided more than [100] miles away." *Id.* The Show Cause Order then alleged that "[a]ll of these prescriptions were written by physicians working at the same clinic and were for amounts ranging from 168 to 240 tablets." *Id.*

To similar effect, the Show Cause Order alleged that on January 16, 2012, Hills' pharmacists dispensed three prescriptions for oxycodone 30 mg tablets in quantities which ranged from 168 to 224 tablets to three persons who "resided more than [50] miles from Hills," which were all "issued by physicians working at the same clinic." *Id.* at 3. The Show Cause Order then alleged that on January 19, 2012, a Hills' pharmacist dispensed 120 oxycodone 30 tablets to a person who resided in Panama City, Florida, which is "located more than [350] miles from" it. *Id.*

The Show Cause Order also alleged that on December 10, 2012, Hills' pharmacists engaged in a further instance of dispensing prescriptions (for 180 oxycodone 30) to two persons with the same last name on the same date "at or about the same time." *Id.* at 3. With respect to these prescriptions, the Government also alleged that "both customers were willing to pay as much as [$7.50] per tablet despite evidence that Hills . . . was now charging double for oxycodone than it charged the previous year." *Id.* And the Show Cause Order further alleged that on December 10, 2011, a Hills' pharmacist dispensed 224 tablets of oxycodone 30 to a resident of Bradenton, Florida, "who willingly paid . . . $1232 for the same prescription he purchased just four months earlier for . . . $896," and that "[b]oth of these prescriptions were also facially invalid inasmuch as they contained no patient address." *Id.*

Finally, the Show Cause Order alleged that in October 2011, Hills' pharmacists dispensed prescriptions for 196 and 240 tablets of hydromorphone 8 mg to two persons. *Id.* The Show Cause Order alleged that the prescriptions, "if taken as directed, far exceeded the recommended [daily] dosage of" the drug. *Id.* The Order also alleged that both "prescriptions were issued by the same physician and one of them was facially invalid . . . as it contained no patient address." *Id.*

Next, the Show Cause Order alleged that Respondent "failed to create and maintain accurate records in violation of 21 U.S.C. 842(a)(5)." *Id.* at 4. More specifically, the Order alleged that: (1) Respondent "failed to complete a biennial inventory as required by 21 CFR 1304.11(c)"; (2) its DEA schedule II order forms did not contain the "receipt date or quantity received in violation of 21 U.S.C. 827(b) and 21 CFR 1305.13(e)"; (3) it "failed to retain Copy 3 of" its schedule II order forms "as required by 21 U.S.C. 827(b) and 21 CFR 1305.13(a) and 1305.17(a)"; and (4) its schedule II records were not "readily retrievable . . . at its registered location in violation of 21 CFR 1304.04(a) and (h)(2)." *Id.*

Finally, the Show Cause Order alleged that a DEA audit of various schedule II drugs found both shortages and overages. The Order alleged that an audit for the period of July 24, 2012 through February 4, 2013 found "a shortage of 4,135" tablets of hydromorphone 4 mg and "an overage of 8,758" tablets of hydromorphone 8 mg. *Id.* The Order also alleged that an audit for the period of June 27, 2012 through February 4, 2013 found an overage of 1,306 tablets of oxycodone 30 mg, and an audit for the period of June 9, 2012 through February 4, 2013 found overages of 113 tablets of morphine 60 mg and 88 tablets of morphine 30 mg. *Id.*

On October 17, 2014, the Order to Show Cause was served on Respondent by delivery to an attorney who was representing it in the investigation, and who had emailed a Diversion Investigator the day before that he would "accept any service of process in that regard for Hills Pharmacy." ALJ Ex. 4. On November 14, 2014, Respondent, through its counsel, filed a request for a hearing with the Office of Administrative Law Judges. ALJ Ex. 2. The matter was then assigned to ALJ Gail Randall, who proceeded to conduct pre-hearing proceedings.[1]

On December 2, 2014, the Government filed its Prehearing Statement. ALJ EX. 7. Of note, the Government's Prehearing Statement contained no additional information beyond that provided by the Show Cause Order as to the identities of the patients whose prescriptions were at issue. *Compare* ALJ Ex. 1, at 2–3, *with* ALJ Ex. 7, at 4–5. Thereafter, Respondent moved for an extension, which the Government did not oppose, and on December 16, 2014, the ALJ granted its motion.

On January 9, 2015, Respondent filed its Prehearing Statement. ALJ Ex. 14. Respondent proposed to call as witnesses, "[a]ny and all patients whose prescriptions were seized by . . . DEA pursuant to the Administrative Inspection Warrant [AIW] executed February 4, 2013 or whose prescriptions for controlled substances were dispensed between January 1, 2011 and February 4, 2013." *Id.* at 3. Respondent further attached to its Prehearing Statement a list of 1,461 persons. *Id.* at Exhibit A. Respondent also proposed to call as witnesses all of the physicians who had issued the prescriptions that were seized pursuant to the AIW and the controlled substance prescriptions that it dispensed between January 1, 2011 and February 4, 2013. *Id.* at 3. Respondent attached to its Prehearing Statement a list of more than 130 doctors. *Id.* at Exhibit B. Respondent further estimated that it would require 45 to 60 days to present its case, exclusive of cross-examination and rebuttal.[2] *Id.* at 9.

On January 14, 2015, the ALJ conducted an on-the-record prehearing conference. Noting that the Government had referred to the patients by their initials, the ALJ ascertained that Government intended to request a protective order. Tr. 6 (Jan. 14, 2015). Continuing, the ALJ noted "the scope of the Respondent's [counsel's] prehearing statement and his inability up to this point to identify the witnesses" and asked the Government if it was "willing to exchange the prescriptions which it intend[ed] to utilize . . . so Respondent can ID the actual patients involved?" *Id.* at 6–7. Government counsel represented that the prescriptions would be sent by Fed Ex that day. *Id.* at 7. Subsequently, the ALJ noted that Respondent's counsel had "proposed in excess of 1,500 named witnesses and approximately 13,500 pages of documents" and asked if this was "still [his] current plan?" *Id.* at 10. Respondent's counsel replied that if "the Court limits the scope of the Government's case to just those prescriptions that are provided to us, I may be able to wean that down slightly." *Id.*

The ALJ then asked Respondent's counsel to explain the purpose of the patients' testimony. *Id.* Respondent's counsel stated that "the Government ha[d] not listed in their list of witnesses any of the patients . . . to whom prescriptions were dispensed and ha[d] not identified any of the physicians who issued [the] prescriptions." *Id.* at 11. Respondent's counsel then explained that it was his position that the Government's Expert's "testimony should be excluded because he hasn't had any contact with any of the patients or prescribers to determine whether or not the red flags that he's identified can be resolved." *Id.* at 11–12. Respondent's counsel then maintained that if the Government's Expert was allowed to testify on these issues, "it would be incumbent upon Respondent to demonstrate by the testimony of the patients regarding the inquiry and discussion between the patients and the pharmacists to resolve any of those red flags as identified by [the Expert], and for those prescribers to testify about their basis for issuing the prescriptions for those particular patients." *Id.* at 12.

On January 15, the ALJ issued a Preliminary Order Regarding Scope Of Proceedings. ALJ Ex. 19. Therein, the ALJ explained that "any of those proposed patient and physician witnesses who are not linked to a prescription transaction which the Government asserts created a 'red flag' present[s] the potential for providing no relevant evidence." *Id.* at 3. However, the ALJ also held that "to the extent warranted by the Government's disclosure (and potentially its case-in-chief at the hearing), the Respondent may seek leave to present evidence from prescribing practitioners and/or patient-customers on the narrow issue of rebutting Government evidence that controlled substances were dispensed in the face of 'red flags' of diversion with no attempts made to contact those witnesses to attempt to resolve the 'red flag(s).' " *Id.* The ALJ thus concluded that "[a]s the proffer stands now . . . an insufficient basis has been presented for presenting the testimony of all of these 1598 proposed witnesses." *Id.* (citing Respondent's Prehearing Statement, at 3 and Exhibits A & B).

Addressing Respondents' proffers of 13,510 pages of documents, the ALJ found "that many of these documents are not relevant to this proceeding." *Id.* at 4. The ALJ thus excluded Respondent from admitting any documents "not linked to inventory practices, the controlled substance audit, or prescription transactions specified in the Order to Show Cause." *Id.* Finally, the ALJ precluded Respondent's Pharmacy Expert from testifying "regarding applicable legal standards and any aspect of the Respondent's legal obligations as a DEA registrant." *Id.* at 5. However, the ALJ held that Respondent's Pharmacy Expert would be permitted to testify as to other areas in accordance with Respondent's proffer. *Id.* at 4.

The same day, the ALJ also issued her Prehearing Ruling. In addition to setting the date of the evidentiary hearing, the Ruling also advised each party that if it chose to amend its witness list to include a new witness, it must file a supplement to its Prehearing Statement and include a summary of the witness's proposed testimony. ALJ Ex. 20, at 3. The Ruling further explained "that witnesses not properly identified and testimony not summarized in prehearing statements or supplements thereto will be excluded at the hearing," and that if either party "wished to raise any issues of inadequacies or ambiguities regarding the proposed witness' testimony . . . [it] may do so by motion." *Id.* Finally, the Ruling specified the date by which all documentary evidence as well as any affidavits were to be provided to both the tribunal and the opposing party.[3] *Id.*

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[1] Respondent raised no objection to the adequacy of service.

[2] Respondent also sought to call the physicians who issued controlled substance prescriptions to the patients listed in Exhibit A after February 4, 2013, as well as the pharmacists who dispensed those prescriptions. ALJ Ex. 14, at 3. It also proposed to call as a witness,"[e]ach and every . . . Diversion Investigator, Special Agent, and/or Task Force Officer who participated in the preparation of the application for the" AIW or the "the execution of the" AIW, and "[a]ny and all witnesses identified in the Government's Prehearing Statement." *Id.* at 4.

Respondent also proposed to call a consultant, who was a former Supervisory Diversion Investigator, who would testify regarding "his knowledge and experience in the investigation, preparation and execution of" AIWs, purported errors in the audits, and Respondent's "procedure for resolving potential 'red flag' issues and compliance with recordkeeping requirements." *Id.* at 3, 5–6. Finally, Respondent proposed to call its own expert who would testify as to "the legal and ethical responsibilities of the pharmacists dispensing prescriptions at" it, the procedures used by it to resolve red flags, and his review of "the prescriptions at issue." *Id.* at 6.

Thereafter, both of Respondent's counsels moved to withdraw; the ALJ granted the motions. ALJ Exs. 24, 25, 29, 31. Subsequently, new counsel entered an appearance and simultaneously moved for a continuance. ALJ Ex. 27, 30. The ALJ granted the motion and continued the hearing for three weeks, scheduling it for March 10 through March 13, 2015. ALJ Ex. 40. In the meantime, both parties filed supplemental prehearing statements, ALJ Ex. 34 & 37, requests for subpoenas, and additional motions.

On March 10 through 12, 2015, the ALJ conducted an evidentiary hearing in Tampa, Florida. *See* Recommended Decision (hereinafter, cited as R.D.), at 5. At the hearing, both parties elicited testimony from multiple witnesses and submitted various exhibits. Following the hearing, the ALJ left the record open so that the Government could submit an affidavit from a Special Agent who was then out of the country. Tr. 613. On April 16, 2015, the Government submitted the affidavit, and on April 21, 2015, the ALJ admitted the affidavit and closed the record. ALJ 52. Thereafter, both parties filed briefs containing their proposed findings of fact, conclusions of law, and argument.

On April 29, 2015, the ALJ issued her Recommended Decision. Therein, the ALJ found that the Government had "proved its *prima facie* case for revocation through the failing of Respondent's accountability practice and its violation of its corresponding responsibility by dispensing controlled substances without first resolving red flags raised by the prescriptions." R.D. 50 (citing 21 CFR 1306.04(a)). The ALJ further held that the testimony of Respondent's pharmacist-in-charge (PIC) on the issue of acceptance of responsibility "lack[ed] credibility." *Id.* at 52. Noting that while its PIC had stated that he had done due diligence in accordance with its protocols prior to dispensing the prescriptions at issue, the ALJ drew an adverse inference based on Respondent's failure to produce evidence to corroborate the PIC's assertion. *Id.* The ALJ thus "conclude[d] that the Respondent's representatives have not accepted responsibility for the full extent of their actions proven by the Government," thus rendering its evidence of remedial measures irrelevant. *Id.* The ALJ then recommended that Respondent's registration be revoked and that any pending applications be denied. *Id.* at 53.

Respondent filed Exceptions to the Recommended Decision and the Government filed a Response to Respondent's Exceptions. Thereafter, the record was forwarded to me for Final Agency Action.

Having considered the record in its entirety, including Respondent's Exceptions (which I discuss throughout this decision), I adopt the ALJ's legal conclusions that Respondent violated the corresponding responsibility rule of 21 CFR 1306.04(a) with respect to many of the prescriptions. I also agree with her legal conclusion that Respondent failed to maintain accurate records as required by 21 U.S.C. 827. And I further agree with her legal conclusion that Respondent has failed to accept responsibility for the misconduct which has been proven on the record of the proceeding. Accordingly, I agree with the ALJ's ultimate conclusion that Respondent has committed acts which render its continued registration inconsistent with the public interest and will adopt her recommendation that I revoke Respondent's registration and deny any pending applications. I make the following

Findings of Fact

Respondent is the holder of DEA Certificate of Registration FH0772257, pursuant to which it is authorized to dispense controlled substances in schedules II through V, as a retail pharmacy, at the registered location of 7730 W. Hillsborough Ave., Tampa, Florida 33615. GX 1. This registration does not expire until October 31, 2016. *Id.* According to Respondent's registration, it is owned by Hills Pharmacy, L.L.C.[4] *Id.* No evidence was put forward as to Respondent's current licensure status with the Florida Department of Health.

The Investigation of Respondent

On February 4, 2013, DEA Investigators executed an Administrative Inspection Warrant (AIW) at Respondent. Tr. 233. The lead Investigator presented the AIW to Respondent's PIC (Mr. George), and obtained various records from Respondent including inventory records, receipt records, and prescriptions. *Id.* According to the Investigator, he asked for two years' worth of records.[5] *Id.* The DI further testified that while Respondent provided him with a perpetual inventory of various schedule II drugs, the document "did have physical inventory dates in there." [6] *Id.* at 235. According to the Investigator, "there was not one date [when] every controlled substance was inventoried." *Id.* Thus, the beginning dates for the drugs that were audited varied. *Id.* at 236.

The DI further testified that as part of executing the AIW, a closing inventory was taken in which various schedule II drugs were physically counted. *Id.* at 237. According to the DI, the closing counts were taken by Mr. George (Respondent's PIC) and were recorded on a document.[7] *Id.;* GX 7. However, the closing inventory was signed by another Diversion Investigator and witnessed by a DEA Special Agent rather than Mr. George. GXs 7 & 16; Tr. 312.

Using the inventories and the records of Respondent's receipts and prescriptions, the DI conducted an audit of Hills' handling of seven schedule II controlled substances. According to the DI, he conducted the audit by adding Respondent's purchases to the initial inventory figures to calculate the quantity of each drug that Respondent was accountable for. Tr. 237. The DI then explained that the "total accounted for" was calculated by using the closing inventory (*i.e.,* the inventory taken on the date of the inspection) and adding the amounts distributed or transferred of each drug. *Id.* According to the DI, the latter was "basically . . . what they filled at the pharmacy" as the Investigators did not "come across" any "sales . . . to other pharmacies." *Id.* He further testified that in calculating Respondent's purchases, "the only numbers that [he] used was stuff that we actually had a physical 222 [form] or [a] CSOS representation" and that he did not count product which was recorded in the perpetual inventory if there was no 222 form for it. *Id.* at 273.

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[3] There were numerous motions filed during the course of the pre-hearing procedures. My discussion of the motions and rulings is confined to those which limited the scope of the proceeding and the evidence that was admissible.

[4] Notwithstanding its representation in its opening statement that it would "show that Hills Pharmacy is owned by Hope" Aladiume and "her brother is Victor Obi Aladiume," Tr. 9, the Government put forward no evidence establishing Hope Aladiume's relationship to Respondent, or whether Victor Obi is her brother. Of note, Victor Obi was the owner of two Tampa pharmacies whose registrations I recently revoked. *Superior Pharmacy I and Superior Pharmacy II,* 81 FR 31310, 31341 (2016). Moreover, Victor Obi served as "the designated representative of the Respondent" during this proceeding. Tr. 4.

[5] According to the DI, "not all of the required records were onsite." Tr. 252. The DI specifically identified the offsite records as including prescriptions from February 4, 2011 through April 2011, inventories from February 4, 2011 through the end of 2011, and receiving records from February 4, 2011 through the end of 2011. *Id.* at 253. The DI further testified that Respondent's attorney had stated that the records were offsite and that the office manager had the key and was not available that day. *Id.*

Respondent, however, disputed that the records were offsite. Its PIC testified that the records were onsite in a locked storage room, but that he had left the storeroom key at home that day, and that when Respondent's owner arrived with the duplicate key "two hours later," "the officers [had] left" so he provided the records to its lawyer. *Id.* at 536.

[6] According to the transcript, the Government asked the DI: "Did you inquire whether Hills had a bi-annual inventory?" Tr. 234. After he explained that he was provided with the above-mentioned perpetual inventory, the Government asked the DI: "So that's how you conclude there was no bi-annual inventory?" *Id.* at 235. The DI answered "correct." *Id.*

Federal law requires, however, that a registrant take biennial and not biannual inventories. 21 U.S.C. 827(a). Moreover, the transcript was not corrected. Thus, I take the transcript as it is.

[7] However, other testimony was to the effect that the closing inventory counts were done by the PIC, another DI, and the Special Agent who signed the inventory as a witness. Tr. 287, 312. Moreover, Mr. George testified that he did not participate in the counting of the drugs on hand. Tr. 535. And he further testified that the Investigators did not tell him that they were "doing the actual count." *Id.* Be that as it may, I find no reason to reject the closing count.

Comparing the "total accountable for" with the "total accounted for" for the seven drugs, the DI found that Respondent had overages in six of the drugs, the most significant being 1,306 dosage units (du) of oxycodone 30 mg and 8,758 du of hydromorphone 8 mg.[8] GX 4. Moreover, Respondent had a shortage of 4,135 du of hydromorphone 4 mg. *Id.*

Respondent disputed the accuracy of the audits. Specifically, its PIC testified that there were controlled substances in the will-call bins. Tr. 536–37. Respondent's PIC then explained that these drugs would be prescriptions that were finished in "vials with the label" and "waiting for the patient to come and collect it." *Id.* at 537. Moreover, a DI testified that the audit team did not count the prescriptions in the will-call bins. *Id.* at 290. He also did not recall if drugs that were quarantined for disposal were counted. *Id.*

Respondent, however, put forward no evidence that there were any drugs quarantined for disposal on the date that the AIW was executed, let alone that any of those drugs were those being audited. Subsequently, the DI testified that "[w]e asked where the controlled substances were," and counted the drugs in the safe because "that's where we were shown." *Id.* at 291.

Respondent's PIC also testified that there were some medications that were returned to the pharmacy's stock when they were not picked up by the customer. Tr. 525. He further identified a document (RX 6, at 3) which lists six instances (by date, RX number, patient name, and quantity) in which a patient apparently did not pick up a prescription for hydromorphone 8 and the drugs were returned to stock. Tr. 525. The PIC testified that he did not know if DEA counted the pills that were returned to stock if they were still on hand. *Id.*

Respondent did, however, introduce into evidence various documents for each of the audited drugs, including a list of the prescriptions that were dispensed, its perpetual inventory for the drug, the invoices and scheduled II order forms for its receipts, and, as explained above, in some instances, a document listing "returns to stock" from patients. As discussed later in this decision, with respect to the overages alleged by the Government as to oxycodone 30 mg and hydromorphone 8 mg, the records show that Respondent placed additional orders that were not counted by the Government and establish that the overages in these two drugs were substantially less than the quantities alleged by the Government. Respondent's records do not, however, call into question the conclusion that it had a large shortage in hydromorphone 4 mg and actually support the conclusion that the shortage was even larger than that alleged by the Government.

The same DI also testified as to other alleged violations. More specifically, the DI testified that several DEA Order Forms for Schedule II drugs (Form 222) were not properly completed, because "[w]hen they don't receive a drug, they need to write a zero if they didn't receive anything." Tr. 255. While the DI did identify an instance in which Respondent had notated the receipt of six packages of methadone 10 mg, he noted that Respondent had failed to include the date that the packages were received. *Id.; see also* GX 10, at 9. He then testified regarding a further order form, on which three of the four line items had been filled in with both the quantity received and the date received, explaining with respect to an entry that was not completed, that the forms "are missing [the] number of packages received, [the] date received." Tr. 255. However, when asked by the ALJ whether the pharmacist would "put the date that he entered the zero" for a similar entry which was left blank (GX 10, at 1, line 2), the DI testified; "I'm not sure about that, but we need the number zero at least." Tr. 256.

The DI also testified that there were some instances in which Respondent provided him with a photocopy of the purchaser's copy of the 222 form, rather than the original which it is required to maintain for a period of two years. *Id.* at 257 (discussing GX 11, at 2). The DI also testified that Respondent did not have any inventory document other than the perpetual inventory documents that its PIC provided. *Id.* at 270. Re-emphasizing the point, the DI subsequently testified that "that's all we had, so we had to use it." *Id.* at 278.

The Allegations of Dispensing Violations

Following the execution of the warrant, another DI provided a CD which contained copies of the schedule II prescriptions[9] that were seized to Robert Parrado, R.Ph., who reviewed them and testified as an Expert for the Government. The DI testified that the Investigators did not obtain the patient profiles (which apparently could have been extracted from the computer which was imaged by the inspection team) and thus did not provide them to Mr. Parrado. Tr. 300.

Mr. Parrado testified that he obtained his B.S. in Pharmacy in 1970 from the University of Florida College of Pharmacy and that he has held a Florida pharmacist's license since 1971. Tr. 14; GX 2, at 1. Mr. Parrado testified that he has practiced as a pharmacist at both community pharmacies as well as hospital pharmacies; he also testified that he had been the pharmacy department manager at multiple pharmacies, including two pharmacies that he owned for approximately 19 years. Tr. 15–16; GX 2, at 1–2.

Mr. Parrado was a member of the Florida Board of Pharmacy from January 2001 through February 2009, and served as both Vice Chairman and Chairman of the Board. Tr. 17; GX 2, at 3. He is a member of the Florida Pharmacy Association, having served as both its President and then Chairman of the Board. GX 2, at 3. He is also a member of the Hillsborough County Alcohol & Drug Abuse Task Force, the National Community Pharmacists Association, and the American Society for Pharmacy Law. *Id.* Finally, he has made numerous presentations on the dispensing of controlled substances by pharmacists, *id.* at 3–7, and has testified as an expert witness for both the prosecution and defense in criminal and administrative matters. Tr. 18.

On *voir dire,* Mr. Parrado explained that he reviewed only the front and back of the prescriptions in forming his opinions, and that while he had also recently been provided with and looked at "some Respondent exhibits [that] looked like partial . . . medical records . . . for about 25 patients," he had already formed his opinion before he reviewed those documents. Tr. 29–30, 32. Mr. Parrado also testified that he did not interview any patients, doctors or pharmacists, and that he was not provided with any information regarding interviews conducted by DEA personnel of the patients, doctors, or pharmacists. *Id.* at 39. Mr. Parrado testified that he did a limited amount of research on his own, which included doing Google map searches to determine how far the patients lived from Tampa, looking to see whether the doctors had a valid license, looking up the pharmacy on the Board of Pharmacy's Web site to determine its ownership and prescription department manager, and looking to see whether the pharmacists had valid licenses and a disciplinary history. *Id.* at 40–42. After an extensive *voir dire* by Respondent's counsel, Respondent objected to Mr. Parrado's being recognized as an expert in community pharmacy practice. *Id.* at 50. The ALJ properly overruled the objection, finding that Mr. Parrado was qualified to testify as an expert in retail pharmacy practice based on "his knowledge, skill, experience, training, and education." *Id.* at 52.

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[8] According to the Government, Respondent had overages of 5 du in methadone 10 mg, 82 or 88 du in morphine sulfate 30 mg, 113 du in morphine sulfate 60 mg, and 2 du in morphine sulfate 100 mg. GX 4, at 1.

[9] According to the DI, the Investigator did not seize "any noncontrolled prescriptions" and "just took [the] [s]chedule [II] scrips." Tr. 299.

On resumption of direct examination, the Government asked Mr. Parrado if there is "a specific protocol" that a pharmacist must follow "before dispensing a controlled substance?" *Id.* at 53–54. Mr. Parrado explained that a pharmacist "has to ensure that the prescription is valid," and that under both the Florida Statutes and federal regulations, "a pharmacist has to ensure the prescription is valid by making sure that it was written by a doctor in the course of his professional practice and that it was for a legitimate medical purpose." *Id.* at 54. Asked what a pharmacist is "required to look for on the actual prescription," Mr. Parrado testified:

> Well, there are certain requirements that have to be on a prescription. What creates a red flag is anything that causes a pharmacist concern about that prescription. . . . [T]here is a thing a pharmacist has to do before he fills a prescription that is called prospective drug review. He has to go over that prescription. He has to evaluate the prescription for appropriateness of therapy, for seeing if there is any therapeutic duplications of medications. Are there any drug/drug interactions? Are there any drug/disease interactions? Is the prescription for—does it show signs of clinical abuse or misuse? You know, that's just a basic thing a pharmacist does before he fills a prescription.
>
> And then, knowing all the requirement of a prescription, what must be on that prescription as far as the patient name and address, the physician's name and address, the DEA number, the name of the medication, the strength, the directions, all those things, the quantity, have to be on that prescription.

Id. at 54–55.

Asked by the Government to explain what a "red flag" is and to give examples, Mr. Parrado testified that "a red flag . . . is anything that would cause a pharmacist concern," and that "[t]here are lots of things that lead to red flags" when a pharmacist is "trying to determine" if a prescription was issued "for a legitimate medical purpose." *Id.* at 55–56. Mr. Parrado then identified multiple red flags, including, what he termed the "first red flag," that being "the drug itself," as there are "known drugs of abuse" that are being "commonly" abused. *Id.* at 56. Mr. Parrado then identified additional red flags to include: the "the dosing"; "[a] person travelling a long distance to acquire that drug"; "a person willing to pay a lot, a lot of money in cash to obtain that drug"; and "a person getting . . . certain cocktails of drugs." *Id.* As to the latter, Mr. Parrado explained that:

> A cocktail is multiple drugs . . . that are known to be abused on the street, and the most common . . . has a name, it's called the Holy Trinity, which would be oxycodone, which is an opioid, a benzodiazepine, which would be a tranquilizer such as Xanax, and a muscle relaxer like Soma. Those three together are well known combinations or cocktails that are abused on the street.

Id.

Next, the Government asked whether "a pharmacist look[s] at the actual amounts that are prescribed when determining whether there's a red flag on that prescription?" *Id.* Mr. Parrado answered that a pharmacist is "required by law . . . to make sure that the dosing is not excessive or inappropriate" and "[t]hat's one of our things that we are trained in." *Id.* at 57. Continuing, Mr. Parrado explained that:

> One of the things that a pharmacist knows or should know is that oxycodone . . . that 80 milligrams a day has been listed in the literature as a lethal dose for an opioid naïve patient. So, when being presented with a prescription for a dose that would exceed 80 milligrams in one day, that pharmacist would need to stop and take a look and verify that the patient is not opioid naïve and has been on a regiment [sic] that has led him to develop a tolerance to that dose.

Id.

Mr. Parrado further identified as a red flag the simultaneous prescribing of two immediate release opioids, which he stated "would be inappropriate therapy." *Id.* at 58. He also identified as a red flag "pattern prescribing," which he defined as "when I see the same medications, the same groups of medications, same combinations of medications in very similar quantities and very similar doses coming out of one . . . clinic." *Id.* Continuing, Mr. Parrado testified:

> When I see multiple people presenting with a very similar group or combination of prescriptions coming from one particular clinic, that is very much a red flag. That's not what happens in the average course of a day in a pharmacy. You don't see groups of people coming in from the same clinic, all getting the same drugs in large quantities and all willing to pay cash.

Id. at 59.

Mr. Parrado identified a further red flag as "multiple people living in one household all receiving the same medications." *Id.* Mr. Parrado then testified: "[i]s it possible? It could be, but it's just not—it doesn't happen on an everyday basis" and that he "would have to resolve [this red flag] before [he] could fill" the prescriptions. *Id.*

Mr. Parrado testified that "the basic way of resolving a red flag is . . . to verify [the prescription] with the prescriber," and that "you consult with the prescriber" and not his staff or nurse, "over your concerns." *Id.* at 60. According to Mr. Parrado, the pharmacist must then "use [his/her] professional judgment" and ask "[d]id I believe what I just heard? . . . [Are] there any red flags in the conversation I just had?" *Id.* Mr. Parrado added that "I've had many, many instances where after a conversation with the physician I said absolutely I'm not going to fill that prescription." *Id.*

Mr. Parrado further testified that some red flags are unresolvable. *Id.* As an example of unresolvable red flags that would lead him to refuse to fill a prescription, he identified "a group of multiple people travelling a long distance, all getting the exact same or very similar prescriptions from one physician and all coming in with very, very large quantities of cash." *Id.* at 60–61. Mr. Parrado then testified that "if you do see a red flag and you can resolve it, you document it on the prescription and then you fill it." *Id.* at 61. Mr. Parrado reiterated that the resolution is written "[o]n the prescription itself." *Id.*

To counter Mr. Parrado's testimony as to the procedures a pharmacist must follow in dispensing controlled substances, Respondent called Dr. Sam Badawi. Dr. Badawi obtained his Doctor of Pharmacy degree from Samford University in 2002, and he is licensed to practice pharmacy in both Alabama and Florida, becoming licensed in the latter State in 2010. Tr. 346. He also holds Juris Doctor degrees from both the Birmingham School of Law (2008) and Stetson University (2014), as well as an L.L.M. (2011) from Stetson in international intellectual property. *Id.*

Mr. Badawi testified that he had worked as a full-time retail pharmacist in Alabama until sometime in 2004 or 2005, when he "transitioned into clinical pharmacy and IV infusion," which involved working "with hospice patients who required intravenous pain prescriptions" and "morphine pumps." Tr. 348. While Mr. Badawi asserted that he continued to work on a part-time basis in retail pharmacy, he subsequently went to work for Amgen, a biotechnology company where his duties involved clinical trial design. *Id.* at 366.

On *voir dire,* Mr. Badawi testified that while he had worked in retail pharmacy for about ten years, four of those years were as an intern. And while he then asserted that he had worked in retail pharmacy "from 02 all the way up to 08, when [he] moved to Florida," *id.* 372, his testimony was that for much of this time he worked only on a "floating" or "part-time basis." *Id.* at 374. Mr. Badawi also acknowledged that when he worked at Amgen, as well as when he worked as a clinical pharmacy director, he did not interact directly with patients. *Id.* at 374–76. He further acknowledged that he had never taught pharmacy or published any articles; he also testified that his experience managing a pharmacy was limited to doing so on an interim basis "for a couple of months." *Id.* at 376.

Mr. Badawi further acknowledged that he is not currently practicing pharmacy. *Id.* at 377. As for his experience testifying as an expert witness, Mr. Badawi testified that it is limited to a single criminal case in which he was listed as a witness but did not testify. *Id.* at 381. While the Government objected to Mr. Badawi's being qualified as an expert witness on the standard of pharmacy practice as it affects the dispensing of controlled substances, the ALJ overruled the objection and deemed him qualified "as an expert in the standard of [pharmacy] practice as to the effective dispensing of controlled substances." *Id.* at 390.

On direct examination, Mr. Badawi testified that when a controlled substance prescription presents a red flag, "[a] reasonable, prudent pharmacist will follow the DEA [Pharmacist's] Manual," which was published in 2010 and which at "page 67" lists criteria that "may be an indication . . . that [the] prescription was not issued for a legitimate medical purpose." *Id.* at 391. Continuing, Mr. Badawi testified that "[a]nd you have six options. And then it tells you what to do." *Id.* at 391–92. Mr. Badawi then referenced a Florida Board of Pharmacy Rule (Fla. Admin. Code r.64B16–27.831), which states that "a prescription that is not issued for a legitimate medical purpose is not a valid prescription," and "gives you five different scenarios" before adding that "in a retail setting, I would follow first the DEA Manual." *Id.* at 392.

Mr. Badawi then testified as to the prevention techniques listed in the Manual, which include "[k]now[ing] your patient . . . what's the story behind that patient," "know[ing] your drug, and know[ing] the prescriber and the DEA." *Id.* at 393. Mr. Badawi asserted that this is what a reasonably prudent pharmacist would do, ignoring that the Manual then states that "[w]hen there is a question about any aspect of the prescription order, the pharmacist should contact the prescriber for verification or clarification." Pharmacist's Manual, at 67.

Mr. Badawi then testified that "[a] red flag is a caution sign for the pharmacist," but "on its face alone does not mean the prescription is invalid." *Id.* at 394. Continuing, Mr. Badawi testified that the Manual says that:

> if any of these criterias [sic] are found . . . the prescription may not be issued for [a] legitimate medical purpose. So actually it's a caution sign. You stop and you look, meaning that you default back on your training, your knowledge, state laws, federal laws, common sense as a professional, and you exercise that professional judgment, meaning a discretion.
>
> So after you stop with that red flag, and then you proceed with caution, and you exercise your discretion. So, if a pharmacist chooses to exercise that discretion favorably by resolving the red flag, then you dispense it. If not, then you don't dispense it.

Id. at 395.

Respondent's counsel then questioned Mr. Badawi about the specific red flags identified by the Government's Expert and how a pharmacist should resolve the red flag. *Id.* at 395–96. As to how a pharmacist should resolve the circumstance where prescriptions are presented "from multiple individuals for the same or similar types of drugs [narcotics] in similar quantities," Mr. Badawi acknowledged that this is a red flag. *Id.* Mr. Badawi then testified that a pharmacist should "fall back to the DEA Manual rules" and "[k]now the patient. So I have two patients with the same address from the same prescriber, so I would actually inquire into the circumstance of these two patients." *Id.* at 396. Continuing, Mr. Badawi added that "then you want to know the doctor" and whether he is "a pain management" or "an ortho surgeon" and "[w]hat's the origination of that prescription?" *Id.* According to Mr. Badawi, if the pharmacist still had doubts despite knowing this:

> you pick up the phone and ask to speak to the prescriber to find out more of the story because sometimes your patients are not going to tell you everything. So I don't want to miss the whole picture. So I would call the prescriber and verify. And if I still have doubts, I would not dispense that prescription. So that goes all under professional judgment, not just looking at the piece of paper and making a decision.

Id. at 396–97. Mr. Badawi maintained, however, that this red flag could be resolved and the prescription could be dispensed. *Id.* at 397.

Respondent's counsel then asked Mr. Badawi whether the fact the drug alone was for oxycodone 30 mg was a red flag of the prescription's potential illegitimacy. *Id.* at 397–98. While Mr. Badawi initially answered that "[t]he drug by itself, no," he then testified that a Board of Pharmacy Regulation "says that if the patient, all he or she is getting [is a] controlled substance, the oxycodone by itself could be under Florida law a red flag because it meets that criteria." *Id.* at 399. Then asked what a pharmacist should do to meet the standard of practice where a patient presents only a prescription for oxycodone 30 mg, Mr. Badawi answered: "Know your patient. So I would actually look into the patient profile history of that patient" to see "if there are any notes being documented in the computer from prior pharmacists that actually dispense [sic] for this individual." *Id.* Mr. Badawi then explained that one of the reasons for reviewing the patient profile is that "there are certain drugs" that you "want to steer away from opioid-naïve patients" and that a pharmacist "want[s to] make sure that the patient is able to tolerate the drug because it's a CNS-depressant." *Id.* at 400. Mr. Badawi also explained that the pharmacist must review the patient profile to determine whether there are any "drug-drug interactions." *Id.* at 401.

Mr. Badawi acknowledged his agreement with Mr. Parrado's testimony that a prescription that calls for the dispensing of a "very large or larger than normal amounts of a narcotic" raises a red flag which requires that the pharmacist make an inquiry. *Id.* at 402–03. He also acknowledged that a narcotic prescription which provides for dosing that is "larger-than-normal," or "larger-than the manufacturer's recommended dosage" also creates a red flag which requires the pharmacist to look at the patient profile and determine if the patient has developed tolerance. *Id.* at 403–04. Mr. Badawi then explained that the doses of patients being treated with narcotics "typically increase[ ] over time to achieve the pharmacological effect and also with respect to tolerance," and it "very common" for a patient to be prescribed both an extended release drug and immediate release drug "for breakthrough pain." *Id.* at 404.

As for the circumstance of a patient presenting prescriptions for two short acting narcotics, Mr. Badawi testified that he "would consider it as a red flag, and I would investigate further, and I would exercise my professional judgment." *Id.* at 418–19. When later asked on cross-examination, what possible explanation there could be for a patient to be prescribed two short-acting opiates together, Mr. Badawi suggested that a patient with kidney failure who is undergoing dialysis three times a week may require a combination because "the drug is being excreted by the kidneys." *Id.* at 435–36.

Mr. Badawi further testified that it is "common for physicians to issue prescriptions for [schedule II] drugs without the address being on the face of the prescription." *Id.* at 406. However, he testified that DEA had issued guidance that a pharmacist is to look at his/her State's rule" to determine whether the patient's address could be added to the prescription. *Id.* at 406–07.

As for how a pharmacist would address the circumstance in which a patient lives "a significant distance . . . from the pharmacy," Mr. Badawi testified that "you want to know the patient, the reason why they're 100 miles way." *Id.* at 407–08. Mr. Badawi then suggested that the patient could be "on a special assignment to MacDill Air Force Base," which is located in South Tampa; that the patient could be a snowbird and that Florida has "a lot of snowbirds"; the patient could be on a three-month job assignment in Tampa or "moving in with his fiancée." *Id.* at 408. Mr. Badawi then testified that he was "not discounting that" this "is a red flag," and that a pharmacist should "investigate more." *Id.* He then maintained that "there is a professional judgment for the pharmacist to exercise, and based on the fact, you act accordingly." *Id.* And he further asserted that the proximity of the prescribing doctor to the pharmacy could explain why the patient who had travelled a long distance was filling the prescription at the pharmacy. *Id.* at 409.

Later, in response to a question by the ALJ, Mr. Badawi maintained that even if the patient was travelling a long distance, if the patient was a regular patron, "that would actually resolve the distance." *Id.* at 437–38. However, after again testifying that the pharmacist should know his patient, the prescriber and the medical condition, Mr. Badawi explained that the pharmacist "may want to inquire more about the patient [sic] reasons for being in hypothetically Tampa." *Id.* at 438.

Asked what types of prescriptions a reasonable pharmacist would "expect to see" when "there is a pain management facility that is seeing a large number of patients for chronic pain," Mr. Badawi testified that a pharmacist would expect the prescriptions to be for "primarily opioids." *Id.* at 416. Then asked what a pharmacist should do "to adhere to the standard of practice . . . and address that issue," Mr. Badawi testified that "when I was there, most of the patients . . . were regulars, and they were getting it actually on set intervals." *Id.* at 416. As for "a new patient, you would go through ID verification [and] [y]ou would actually have them fill out more of a history, diagnosis." *Id.* at 417. Mr. Badawi then agreed with Respondent's counsel's suggestion that knowing that the clinic administered random drugs screens would "assist a reasonable pharmacist." *Id.* Asked what other information a pharmacist would want to know about the practices of a pain management clinic, Mr. Badawi testified that a pharmacist would want know that the practitioners "hold a valid DEA license" and that the clinic has "an active state license to conduct business." *Id.* at 418. Continuing, Mr. Badawi explained that "you utilize the [Prescription Drug Monitoring Program] and the patient profile. So it's the totality of the circumstances, not just one angle, like a tunnel vision, when you actually want to verify these red flags." *Id.*

Mr. Badawi then testified that standing alone, none of the red flags identified by the Government's Expert render a prescription invalid. *Id.* at 419. He then explained that "[r]ed flags are meant for the pharmacist to stop and inquire. So, now, if you have a combination thereof, not just one flag, maybe the weight of the inquiry is probably more than just one red flag." *Id.* at 419–20. He then testified that none of the red flags or combinations thereof identified by the Government's Expert required that the pharmacist reject the prescription. *Id.*

Mr. Badawi then testified that with the exception of a Board rule which requires a pharmacist to make a photocopy of a patient's identification, or if a copier is not available, to document descriptive information on the back of a prescription, there is no requirement that a pharmacist document his resolution of a red flag on the prescription. *Id.* at 421. Asked whether it is the standard practice for a pharmacist to document how he/she resolved every red flag, Mr. Badawi answered:

> . . . I don't know if you could document every single thing. I mean, you pick your battles. You want to document the major issues, and documentation nowadays, especially with these computer systems that would make you approve a prescription via a thumbprint scan, you don't even have to put a code on the computer anymore. These electronic records are kept.
>
> I would rather, as a reasonable, prudent pharmacist, and to benefit my other colleagues who are working after my shift, to have access to this documentation is to have it on the computer under the patient notes so they can see what I've done versus the paper trail.

Id. at 422. However, when asked on cross-examination if it is "within the standard of practice . . . to not document how a red flag is resolved," Mr. Badawi answered: "No, it is not in the standard of practice to make a blanket statement and not to document any red flags that are being resolved." *Id.* at 436–37.

Mr. Badawi also testified that he had attended a presentation by Mr. Parrado two years earlier on dispensing controlled substances, during which Mr. Parrado "said there is a lot of gray area, it's not black or white, and to always use your professional judgment." *Id.* at 425. According to Mr. Badawi, during the presentation Mr. Parrado did not mention that the distance a patient travels is a red flag and that Mr. Parrado also told the attendees that "there is no ceiling on" the quantity of narcotics that a patient can be prescribed. *Id.* at 426. Mr. Badawi also testified that Mr. Parrado did not identify as a red flag the circumstance of a prescription missing a patient's address. *Id.* at 426–27. He also asserted that Mr. Parrado did not identify as a red flag the circumstance of patients residing at the same address. *Id.* at 427. While the Government objected to Mr. Badawi's testimony regarding the presentation on the ground that it had not been disclosed in advance of the hearing, to which Respondent's counsel asserted that this testimony was offered to impeach Mr. Parrado, *id.* at 424–25, 427; the ALJ overruled the objection. *Id.* at 427.

On cross-examination, Mr. Badawi acknowledged that he had not looked at any of the prescriptions. *Id.* at 430. Nor did he look at any of the patient profiles. *Id.* Asked if "traveling hundreds of miles to see a physician is a potential red flag," Mr. Badawi testified: "It's not a potential red flag. It is a red flag." *Id.* When then asked if travelling hundreds of miles to see a physician whose clinic was affiliated with the pharmacy was a red flag, *id.*, Mr. Badawi testified that the affiliation raised a separate issue regarding possible "kickbacks and Stark laws," but that "has nothing to do with the controlled substance dispensing." *Id.* at 431. However, after again agreeing that distance "is a red flag," Mr. Badawi stated that "[i]f they're sending patients in the back door and the pharmacists suspect that's a red flag, that's a separate issue on its own." *Id.*

On questioning by the ALJ, Mr. Badawi acknowledged that there are some red flags that are not resolvable such as a prescription for some astronomical number of a drug such as morphine. *Id.* at 439. As an example, he testified: "a 12-year old with [a] high doses of opioids, maybe in the hundred, for a broken bone. That seems excessive. So I would actually consult with the physician." *Id.* Mr. Badawi did not, however, explain what action he would take if the physician asserted that the prescription was legitimate.

As another example of an unresolvable prescription, Mr. Badawi offered where "there is any drug-drug interactions that would deem that the prescription is not in the best interests of the patient." *Id.* However, in Mr. Badawi's view, this involved a "medical issue" and "therapeutic appropriateness" and "not necessarily the validity of the prescription." *Id.* As an example, he then identified a patient being prescribed opioids when she was pregnant because even though the prescriptions may have been valid "medically speaking," the fetus could be born addicted. *Id.* at 440. Mr. Badawi did not, however, address whether the simultaneous prescribing of drugs such as oxycodone 30, alprazolam, and carisoprodol also raises an issue of drug-drug interactions.

As between Mr. Parrado's and Mr. Badawi's testimony, there was substantial agreement on a number of issues. Where, however, there are areas of disagreement, I generally find that Mr. Parrado's testimony was more credible based on his years of service on the Florida Board of Pharmacy and because his experience in retail pharmacy is far lengthier and more current than that of Mr. Badawi.

The Prescription Evidence

At the hearing, the Government introduced into evidence copies of the front and back of 83 prescriptions for schedule II controlled substances which it alleged were dispensed by Respondent's pharmacists in violation of 21 CFR 1306.04(a) because they presented red flags which were not resolved. *See* GXs 3, 13, 14, and 15. Nearly all of the prescriptions were issued by physicians at the 24th Century Medical Center,[10] which was located at 7747 W. Hillsborough Ave. in Tampa, *id.*, a short walk from Respondent. According to a DEA Intelligence Research Specialist (IRS) who reviewed data that came from Respondent's dispensing software, 1,460 patients filled a total of 4,287 schedule II prescriptions at Respondent between January 3, 2011 and February 2, 2013. GX 12, at 2; Tr. 219. The IRS further determined that 3,867 of these prescriptions—more than 90 percent—were written by six doctors who worked for Victor Obi. Tr. 219, 223; GX 12, at 2. These doctors include S. A.-H., P.C., R.R., H.D., V.S., and J.E., who worked at the 24th Century clinic. According to the online records of the Florida Department of Health, 24th Century is a pain management clinic which has been owned by Mr. Obi since January 4, 2010.[11]

For example, the Government introduced a prescription issued by Dr. P.C. of the 24th Century Medical Center on July 28, 2011 to T.V. for 210 oxycodone 30 mg, which Respondent filled the same day. GX 3, at 1. While T.V.'s address was not written on the prescription, the prescription bears an address label listing T.V.'s address as being in Pensacola, Florida, a distance of 472 miles from Respondent. R.D. at 6.

Mr. Parrado testified that the prescription presented several red flags, including the lack of the patient's address; that it was for oxycodone 30 mg, a known drug of abuse; and that it was for a minimum of 180 milligrams a day, which is "well above the 80 milligrams threshold" and "a very high dose" and large quantity. Tr. 63. Mr. Parrado then noted that the patient's address was in Pensacola, 472 miles from Respondent. *Id.* at 64; R.D. at 6.

Mr. Parrado testified there was no indication on the prescription that "anything was done . . . except that it was filled." *Id.* Asked whether it was possible to resolve the various red flags, Mr. Parrado replied that it was possible, "but it would have taken a lot of investigation" and that he "would have had to have a good reason why that patient had to travel all the way to this clinic to get a prescription filled." *Id.* at 64–65. Continuing, Mr. Parrado stated that he could "see if a patient is driving that far because they're . . . see[ing] a specific physician that has a specialty that's not available anywhere else." *Id.* at 65. Mr. Parrado subsequently testified that he was not aware that the physician has any specific specialty. *Id.* at 68. After the ALJ properly overruled Respondent's counsel's objection that Mr. Parrado was testifying beyond the scope of his expertise, the ALJ asked "what would indicate on a prescription to you as a pharmacist of what you're looking for in this physician?" *Id.* at 69. Mr. Parrado answered:

> . . . When I look at a prescription, I look and see where it came from. . . . You know a pharmacist has to exert his professional judgment on all prescriptions before he fills them. So I would be looking to see . . . I'm looking at a high dose of a very strong opioid narcotic. Where is that coming from . . . ? Is that coming from a cancer center, from an orthopedic office, somebody just had a big surgery? . . . I look for things like that, and I didn't see anything like that on here or I didn't see anything on this prescription that would indicate that a pharmacist had called to verify any of those things.

Id. at 69–70.

Next, on August 4, 2011, Dr. S.A.-H., also of the 24th Century Medical Center, issued a prescription to J.P. for 196 oxycodone 30 mg; Respondent filled the prescription the same day. GX 3, at 2. Here too, J.P.'s address was not written on the prescription; rather a label was attached which listed J.P.'s address as being in St. Augustine, Florida, a distance of 196 miles from Respondent. *Id.;* R.D. at 6.

Asked if the prescription presented any red flags, Mr. Parrado identified the lack of the patient's address; that is was written for oxycodone 30, "a known drug of abuse"; that "it's a very high quantity"; that the patient lived "a rather good distance" from Tampa; that it came from the 24th Century clinic; and that "[t]he patient paid $784 in cash." *Id.* at 70–71. As to the cost of the prescription, Mr. Parrado testified that:

> You don't see people paying $784 in cash. You tell a person they have a $50 co-pay and

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[10] Throughout this decision, the 24th Century Medical Center is also referred to as the 24th Century clinic and 24th Century.

[11] I take official notice of the online records of the Florida Department of Health which establish that Victor Obi-Anadiume is the owner of 24th Century Medical Center and has been since January 4, 2010. Under the Administrative Procedure Act (APA), an agency "may take official notice of facts at any stage in a proceeding-even in the final decision." U.S. Dept. of Justice, *Attorney General's Manual on the Administrative Procedure Act* 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA's regulation, Respondent is "entitled on timely request to an opportunity to show to the contrary." 5 U.S.C. 556(e); *see also* 21 CFR 1316.59(e). Respondent may dispute my finding by filing a properly supported motion within fifteen calendar days of this Order which shall commence on the date this Order is mailed.

> they go ballistic on you. And for a person to willingly pay $784 and not have any documentation as to why they did that and to see that over and over every day is a concern to me. . . . That's a red flag that I couldn't resolve.

Id. at 71. Mr. Parrado then explained that "there were multiple red flags on here" and that "[a]ny attempt to have . . . done anything with them to resolve them would have been documented on the prescription." *Id.* at 71–72. However, Mr. Parrado "did not see any documentation on this prescription that led me to believe anything was done." *Id.*

Also on August 4, 2011, Dr. P.C. of the 24th Century Medical Center issued a prescription to T.P.—who has the same last name as J.P.—for 224 oxycodone 30 mg; Respondent filled the prescription the same day. GX 3, at 3. Here too, T.P.'s address was not written on the prescription; rather a label was attached which listed her address as also being in St. Augustine, Florida. *Id.;* R.D. at 6. Moreover, Respondent's dispensing software assigned the number 2037897 to J.P.'s prescription and the number 2037898 to T.P.'s prescription. GX 3, at 2–3.

Asked if T.P.'s prescription presented any red flags, Mr. Parrado testified that "[h]ere we have two people with the same last name traveling from St. Augustine . . . to get very similar prescriptions." Tr. 72. After noting the quantity of each prescription, Mr. Parrado testified that there were "the same red flags as before. No address, the known drug of abuse, the high quantity, traveling the long distances" and that T.P. "paid $896 in cash." *Id.* According to Mr. Parrado, T.P.'s prescription "was the very next prescription entered" in the dispensing software after J.P.'s. *Id.* at 74.

Also on August 4, 2011, Dr. P.C. issued a prescription for 240 oxycodone 30 to W.J.; Respondent filled the prescription the same day. GX 3, at 4–5. Here too, W.J.'s address was not written on the prescription and had been added by a label which listed his address as being in San Antonio, Florida, a distance of 36 miles from Respondent. *Id.;* R.D. 6.

Mr. Parrado testified that the prescription presented red flags which included the lack of the patient's address; that the drug was for oxycodone 30, a known drug abuse; that the quantity was very high; that the patient was travelling from a town which is "40 miles from Tampa"; that the patient paid $960; that the prescription was written by a doctor from the same clinic; and that the prescription number (2037895) preceded the numbers on the prescriptions presented to J.P. and T.P. Tr. 75. Mr. Parrado explained that "[t]hese were all filled on the same day, so you have multiple prescriptions coming in from people travelling a long way, from the same clinic, for very similar drugs, and paying in cash, very large quantities of cash." *Id.* at 75–76. Mr. Parrado then testified that there was no evidence on the prescription that the red flags were resolved. *Id.* at 76.

On July 29, 2011, Dr. S.A.-H. issued a prescription for 140 oxycodone 30 to W.D.; Respondent filled the prescription the same day. GX 3, at 6–7. Here again, the prescriber had not written W.D.'s address on the prescription and his address was added by label which listed it as being in St. Cloud, Florida, a distance of 92 miles from Respondent. *Id.; see also* R.D. at 6. Mr. Parrado testified that the prescription presented "the exact same red flags as . . . the previous prescriptions," and that there was no documentation that the red flags were resolved. Tr. 76–77.

Mr. Parrado provided testimony to the effect that other prescriptions in GX 3 presented the same red flags as he had previously identified. These included two prescriptions written on July 29, 2011 by Dr. P.C. for 168 oxycodone 30 to C.D. and 224 oxycodone 30 to D.M., as well as two prescriptions written by Dr. S.A.-H. the same day for 168 oxycodone 30 to B.P. and 224 oxycodone 30 to C.C. GX 3, at 8–15. Respondent dispensed the prescriptions the same day. GX 3, at 8–15. As written, none of the prescriptions contained the patient's address. *See id.* at 8, 10, 12, and 14. However, the prescriptions bear labels which show that C.D. and B.P. lived in Gainesville, 134 miles from Respondent; D.M. lived in Hudson, 36 miles from Respondent; and C.C. lived in Spring Hill, 42 miles from Respondent. *See id.; see also* R.D. at 6.

Mr. Parrado testified that these prescriptions raised an additional red flag, in that he was "starting to see a pattern . . . coming from this one clinic of the same prescriptions" and that "[t]here is no individualization of therapy, which is important." Tr. 80. He also testified that he did not see any evidence that the red flags were resolved. *Id.* at 82.

On April 21, 2011, Dr. P.C. issued a prescription for 196 oxycodone 30 to C.B., which Respondent filled the same day. GX 3, at 16. Again, Dr. P.C. did not write C.B.'s address on the prescription. *Id.* According to the address label, C.B. lived in Big Pine Key, which is near Key West and a distance of 400 miles from Respondent. *Id.;* R.D. at 6. Mr. Parrado testified that he did not see any evidence that the red flags were resolved. *Id.* at 82.

Also on April 21, 2011, Dr. R.R. issued a prescription for 224 oxycodone 30 to S.S., which Respondent filled the same day. GX 3, at 17. Dr. R.R. did not write S.S.'s address on the prescription. *See id.* According to the address label, S.S. lived in Lakeland, a distance of 44 miles from Respondent. *Id.; see also* R.D. at 7.

After testifying that the prescription raised the same red flags as the previous prescriptions, Mr. Parrado explained that there was documentation on the prescription that the pharmacist had dispensed two different brands. Tr. 82–83; *see also* GX 3, at 17. However, Mr. Parrado did not see any evidence that the red flags were resolved. *Id.* at 83.

Pages 18 through 25 of Government Exhibit 3 contain copies of eight prescriptions which were also written on April 21, 2011 by physicians from the 24th Century clinic for oxycodone 30 (in quantities that range from 140 to 240 tablets) and filled the same day. As with the previous prescriptions, none of the prescribers wrote the patient's address on the prescription; instead, the prescriptions bear a label with the address. *See* GX 3, at 18–25. Asked whether these prescriptions presented any additional red flags, Mr. Parrado testified that:

> It's just another day of doing the same thing. Yeah, could something like this happen once occasionally a person travels a long way and pays cash? Of course. Does it happen consistently day after day after day? No. That's what would be a nonresolvable red flag.

Tr. 84.

The Government then asked Mr. Parrado if he knew where Hudson is in relation to Tampa.[12] Tr. 85. Mr. Parrado answered that it is 30 to 40 miles on the way to New Port Richie (which was the town or residence of one of these patients). *Id.* The Government then asked why it would "be a red flag if it's just 30 miles?" *Id.* Mr. Parrado explained:

> It's not so much just the red flag, it's the rapidity of people coming from other cities. You know, there's a lot of physicians' office, a lot of pharmacies between Hudson and Tampa. Why did they choose this pharmacy? That would have been the red flag I would have wanted resolved.

Id. Mr. Parrado then testified that he did not see any documentation that the red flags presented by the April 21, 2011 prescriptions had been resolved. *Id.*

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[12] None of the patients whose prescriptions are reproduced at pages 18 through 25 resided in Hudson. *See* GX 3, at 18–25. Rather, the patients were from Tampa, Wildwood (79 miles), Dunedin (14 miles), Palm Harbor (14 miles), New Port Richey (25 miles), Port Richey (26 miles), Gainesville (134 miles) and Lutz (18 miles). R.D., at 6–7.

Next, the Government asked Mr. Parrado about the price of a prescription written by Dr. H.V.D. (also of 24th Century) on January 16, 2012 for 224 tablets of oxycodone 30, which Respondent filled the same day.[13] Tr. 86. The price of the prescription was $1,232. *Id.; see also* GX 3, at 28. The Government then asked Mr. Parrado if he had "any independent knowledge of what oxycodone normally sold for at that time?" Tr. 86. Respondent objected to the question on the basis that there was no foundation as to Mr. Parrado's knowledge. *Id.* While the ALJ sustained the objection she allowed the Government to establish a foundation. *Id.* at 87. The Government then asked Mr. Parrado if, in his "view as an experienced pharmacist," the price was "a red flag." *Id.* Mr. Parrado answered "yes," and explained:

> It's a very high price. I do know that about this time, in this timeframe, 2012, average wholesale price of oxycodone ran anywhere between $33 100 to maybe, depending on what wholesaler you went to, it could run as high as $150, $200 100. But that would still—this price would still be far exceeding anything that I would have ever, ever considered charging.

Id. at 87–88. Mr. Parrado subsequently testified that "I cannot say in my 40 plus years as a pharmacist I have ever sold a prescription for $1,232 cash. That's just not something I've ever seen in my practice." *Id.* at 89. Mr. Parrado then testified that he was practicing pharmacy "[i]n 2012." *Id.* Asked to look at the prescriptions reproduced at pages 29 and 30, both of which were written by doctors with 24th Century, Mr. Parrado testified that they presented the same red flags.[14] *Id.*

Next, the Government asked Mr. Parrado about two Dilaudid (hydromorphone[15]) prescriptions which were written by Dr. R.R. of 24th Century on October 10 and 13, 2011, which Respondent filled. GX 3, at 31–32. The first prescription authorized the dispensing of 240 tablets of Dilaudid 8 mg to D.K.; the second authorized the dispensing of 196 tablets of Dilaudid 8 mg. to G.C.[16] *See id.* The labels for both prescriptions included the initials "KG," thus indicating that they were dispensed by Kasey George, Respondent's PIC.

Asked whether these prescriptions presented any other red flags, Mr. Parrado testified:

> Yeah. For starters, the drug. Dilaudid 8 milligram, extremely, extremely potent opioid. From my education, experience, and training, the average daily dose of Dilaudid would be probably between 12 and 24 milligrams a day. It would be a dose that would be a high dose because mostly people don't take Dilaudid 8 milligrams unless they're in a terminal stage of cancer. . . . [T]hat's just a drug that's very rarely dispensed anymore because of the potency, especially in that quantity. And to see a patient come in and get 200 plus of these tablets would be a . . . concern. To see multiple prescriptions for 200 tablets would be almost a nonresolvable red flag to me.

Tr. 90. Mr. Parrado further clarified that his opinion regarding the quantity applied to both prescriptions. *Id.* at 91. He then testified that he saw no evidence that the red flags had been resolved and added that the dose "is almost double the recommended upper daily dose." *Id.*

On January 19, 2012, Dr. R.R. of 24th Century issued a prescription for 120 oxycodone 30 to S.D. GX 3, at 33. According to the address label (Dr. R.R. again not having written the patient's address on the prescription), S.D. lived in Panama City, Florida. GX 3, at 33. Mr. Parrado testified that Panama City is in the western panhandle of Florida, and the parties stipulated that it is 331 miles from Respondent. Tr. 92; R.D. at 7. Mr. Parrado again found no evidence that the red flags had been resolved. Tr. 93.

Continuing, the Government questioned Mr. Parrado about prescription labels found at pages 34 and 35 of its Exhibit 3 which showed the prices Respondent was charging for oxycodone 30 in late April 2011 and in early December 2011. Specifically, the evidence showed that in late April 2011, Respondent was charging $3.75 for a tablet of oxycodone 30, but that in early December 2012, it was charging $7.50 a tablet. GX 3, at 34–35. Mr. Parrado explained that he determined the price per tablet because he knew "in that time frame that the wholesale costs had not doubled." Tr. 96. Mr. Parrado then testified that the price Respondent charged raised a red flag. *Id.* at 96–97. However, after recognizing that "we don't have the prescription," the Government did not ask whether there was any evidence that the red flags had been resolved. *Id.*

The last page of Government Exhibit 3 contains the front and back of a prescription (dated April 25, 2011) which was written by a doctor from Tampa who was not affiliated with 24th Century. GX 3, at 36. The prescription authorized the dispensing of 120 tablets of methadone 10 mg for pain to B.V. but did not list B.V.'s address. *Id.* Of note, the front of the prescription contains the notation: "verified by Dave" with the date and time. *Id.* The back of the prescription contains a photo copy of a state-issued identification card and the prescription label which list B.V.'s address as Riverside, Florida. *Id.* According to the stipulation, Riverside is 200 miles from Respondent. R.D. at 7.

After noting that the prescription "had some documentation that somebody verified something," Mr. Parrado testified to the effect that it was unclear what the pharmacist verified. Tr. 97; *see also id.* ("What does this mean? What did they verify? Who is this somebody? Was that the prescriber? You know, what were they verifying?"). Then asked what red flags were presented by the prescription, Mr. Parrado testified:

> Methadone . . . it is a drug that . . . it's being abused on the street. There's a lot of concern. I have a lot of concern about the use of . . . methadone because of the pharmacokinetics of the drug and the way it acts on patients. And . . . taking two tablets every 12 hours would probably be okay. I would want to verify with the doctor if the patient had developed a tolerance to this. I've seen people that have overdosed and died on methadone on the third dose of methadone because of the kinetics of that drug.

Id. at 97–98. Subsequently, Mr. Parrado reiterated his testimony that he did not know what the pharmacist had verified with respect to the prescription and that he did not see any evidence that "red flag of distance" had been resolved. *Id.* at 102.

Thereafter, the Government showed its Exhibit Number 13 to Mr. Parrado. This exhibit includes 20 prescriptions for schedule II narcotics including oxycodone 30, MS Contin 30 (morphine sulfate continuous release), and Dilaudid in both eight and four milligrams per dosage unit. *See generally* GX 13. Each of the prescriptions was issued by a physician with 24th Century between April 14 and 20, 2011, and on each of the prescriptions, the patient's address had not been written on the prescription but had been added by a label. *Id.*

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[13] Here too, the patient's address was added by a label and had not been written by the physician; the label shows that the patient lived in Floral City, Florida, 63 miles from Respondent. GX 3, at 28.

[14] The first of these prescriptions was written by Dr. R.R. on January 18, 2012 for 224 oxycodone 30. GX 3, at 29. The patient's address was added by a label and showed that he lived in Dunnellon, Florida, 88 miles from Respondent. *Id.; see also* R.D. at 7. The patient paid $1232 for the prescription. GX 3, at 29.

The second prescription was written by Dr. P.C. on January 19, 2012 for 168 oxycodone 30. GX 3, at 30. The patient's address was added by a label and showed he lived in Inglis, Florida, 80 miles from Respondent. *Id.; see also* R.D. at 7. The patient paid $966 for the prescription. GX 3, at 30.

[15] Mr. Parrado testified that "[h]ydromorphone is the generic name of Dilaudid." Tr. 92.

[16] As before, Dr. R.R. did not write either patient's address on the prescription. GX 3, at 31–32. Labels attached to the prescriptions show that D.K. lived in Clearwater, a distance of 19 miles from Respondent, and that G.C. lived in Largo, a distance of 21 miles from Respondent. *See id.;* R.D. 7.

Also, each prescription presented the issue of the distance travelled by the patient, with the closest any patient resided being in Tarpon Springs, a distance of 18 miles to Respondent. *See* GX 13, at 23; R.D., at 7. The other patients lived in Brooksville (46 miles), Gainesville (134 miles), Newberry (145 miles), Ocala (100 miles), High Springs (158 miles), Spring Hill (42 miles), Sarasota (58 miles), Weeki Wachee (48 miles), Silver Springs (107 miles), Dunnellon (88 miles), and Lecanto (70 miles). *See generally* GX 13; R.D. at 6–7.

Asked by the Government whether the GX 13 prescriptions raised the same or additional red flags, Mr. Parrado answered: "[i]t's all the same." Tr. 105. After noting that one of the prescriptions was for a patient from Dunnellon, Mr. Parrado then testified that he did not see any indication that the red flags had been resolved. *Id.* at 105–06.

Next, the Government asked Mr. Parrado about two prescriptions issued on January 8, 2013, by Dr. P.C. to B.W. and filled by Respondent the same day. Tr. 107–8; GX 14, at 1–5. The prescriptions were for 100 Dilaudid 8 mg and 60 methadone 10 mg. GX 14, at 1–4. While Dr. P.C. was not affiliated with 24th Century, he also failed to include B.W.'s address on the prescriptions; however, both prescriptions bear an address label which lists B.W.'s address as Tallevast, Florida, which is 54 miles from Respondent. *Id.,* at 2, 4; R.D. 7. The evidence also showed that B.W. presented a Florida Identification Card. GX 14, at 5.

Asked if these prescriptions presented any red flags, Mr. Parrado testified that the dosing instruction on the Dilaudid prescription called for taking one tablet every four hours, which would result in a daily dosage of 48 milligrams, "double the upper recommended dose." Tr. 107. Mr. Parrado then noted that the prescriptions raised an additional and serious concern because both Dilaudid and methadone were being prescribed and both drugs "are immediate release opioids . . . which could contribute to respiratory depression." *Id.* Mr. Parrado subsequently testified that B.W.'s address and presentation of an identification card raised additional issues that "a reasonable pharmacist [would] want to investigate." *Id.* at 110.

The record includes prescriptions for 75 Dilaudid 8 mg and 90 methadone 10 mg issued on January 21, 2013, by Dr. E.G.-R. (who was not affiliated with 24th Century) to T.F. of Brooksville; Respondent filled the prescriptions the same day. GX 14, at 7–8. While the back of each prescription includes a handwritten notation dated "1/21/13," *id.* at 8, Mr. Parrado testified that he did not "know what that is" and the notation "doesn't tell me anything." Tr. 110. After testifying that the distance in miles between Brooksville and Tampa is "maybe 30, 40 miles," Mr. Parrado testified that it is "not so much the distance" but that "it's not an easy drive" as there are "a lot of stop lights and a lot of traffic to get" to the doctor's clinic, which was located "several miles" from Respondent. *Id.* at 111. Mr. Parrado then explained that he would want to know why the patient had "come there," that he "would have had concern" as to the methadone dose, and that he "would have wanted to verify" why the doctor had prescribed "two immediate release medications." *Id.* However, Mr. Parrado did not see any evidence that the red flags were resolved. *Id.*

Mr. Parrado testified that while a prescription (GX 14, at 11–12), which was written by Dr. S.A.-H. of 24th Century, was for "only 90 tablets" of oxycodone 30 mg, the patient's address was in Middleburg, Florida, which is "a good ways from Tampa." Tr. 111. According to the stipulation, Middleburg is 175 miles from Tampa. R.D. at 7. Mr. Parrado also testified that the price of the prescription, "$675 for just 90 tablets[,] seems like a very high price." Tr. 112.

Aside from the first four prescriptions in GX 14, each of the remaining 16 prescriptions was written by a doctor with the 24th Century clinic. *See* GX 14, at 11–42. Asked if the red flags of "the distance where the patient lived" and "the fact that they came from the same clinic" were "inherent in all" of the 16 prescriptions, Mr. Parrado answered "yes," and that he did not "see any evidence of any kind of documentation" that the red flags were resolved. Tr. 112–13.

While the back of each of the prescriptions issued by the 24th Century physicians also contains checkmarks or scribble, Mr. Parrado testified that "that just looks like they're verifying the quantity and possibly the directions, but . . . not addressing the red flag." *Id.* at 113. Mr. Parrado then explained that "[i]t's common for pharmacists when they're verifying a prescription . . . before a prescription can be dispensed, the pharmacist has to look at [it] to make sure the right drug is being dispensed, the right quantity, directions are correct on the label. That looks like that's what was being checked off there." *Id.*

Government Exhibit 15 contains an additional 13 prescriptions. GX 15. The first two prescriptions were written by Dr. V.S. on January 28, 2013 to J.A. and were for 56 Adderall 30 mg and 84 Dilaudid 8 mg. *Id.* at 1, 3. While the prescriptions list Dr. V.S.'s affiliation as the MD Plus Clinic in Lakeland, Florida, *id.,* Dr. V.S. was also listed as one of the prescribers affiliated with 24th Century. GX 3, at 33; GX 13, at 1. *Id.* On neither prescription did Dr. V.S. write J.A.'s address; according to the labels attached to the back of each prescription, J.A. resided in Winter Haven, which is 60 miles from Respondent. GX 15, at 2, 4; R.D., at 7.

Mr. Parrado testified that Adderall is a stimulant and that the patient was "getting an upper and downer together." Tr. 114. Asked if this was a red flag, Mr. Parrado testified that "I would have wanted to know why they were giving an upper and a downer together. Maybe the patient was having some kind of narcolepsy . . . from one drug to cause him to need a stimulant from the other side, but I would have expected to see some documentation on that." *Id.* Mr. Parrado then testified that Winter Haven is "a very long way from Tampa," although he erroneously stated that the distance was "a hundred plus miles." *Id.* He then testified that he did not see any evidence that the red flags were resolved. *Id.* at 115.

As for the rest of the prescriptions in GX 15, the patients lived in Citra (117 miles from Respondent), Brooksville (46 miles), Gainesville (134 miles), Tarpon Springs (18 miles), Ocala (100 miles), Nokomis (79 miles), and Newberry (145 miles). GX 15, at 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, and 26. Mr. Parrado testified that the distances travelled by the patients raised red flags and that he did not see any evidence on the prescriptions that there was any attempt to resolve the red flags. Tr. 116.

Asked by the Government whether Respondent's pharmacists "exercise[d] the appropriate standard of care in the State of Florida," *id.* at 119–20, Mr. Parrado testified:

> No. In my opinion, there are multiple things that a pharmacist has to do before he dispenses a prescription. He has to establish the appropriateness of the therapy. He has to discuss the . . . excessive and inappropriate quantities. He has to assess the therapeutic duplication of the two immediate release medications, all of which are in the laws and rules of the practice of pharmacy.
>
> * * *
>
> There are probably four or five other notations in the Florida law that things the pharmacist would have had to have done to verify the prescription and make sure it was

> appropriate and everything was correct before he dispensed it, and I didn't see where any of that was done. Therefore, I didn't think he reached the standard of care.

Id. at 120. After a series of objections to the Government's questions were sustained by the ALJ, Mr. Parrado subsequently testified that he "would not have dispensed these [prescriptions] without having resolved any of the red flags." *Id.*

On cross-examination, Mr. Parrado acknowledged that every red flag he had "talked about . . . could potentially be resolved." *Id.* at 127. He further acknowledged that there are millions of people who do not have insurance and must pay for their prescriptions with cash. *Id.* at 131. However, when asked whether he had ever filled a controlled substance prescription for someone who did not have "insurance to cover their [sic] prescription," Mr. Parrado answered that he was not going to give "a yes or no answer because . . . a person who . . . can't afford insurance . . . is not going to pay 1,200 or 1,300 dollars for a prescription." *Id.* at 132. Mr. Parrado further testified that whether the prescription was paid for with cash, credit card, or check, it's "all the same to me." *Id.* at 133.

After Mr. Parrado reiterated his earlier testimony that he "didn't see where anything [as to the resolution of red flags] was documented," Respondent's counsel asked if it is "true that Florida does not require a pharmacist to document the resolution of red flags on the face of the prescription?" *Id.* at 134. Mr. Parrado answered: "I would never document it on the face, I'd write it on the back." *Id.* at 135. Mr. Parrado then acknowledged that "there's no regulation that says you have to, but that's just the standard of practice and has been for decades." *Id.* When then asked whether a pharmacist could document the resolution of a red flag "somewhere other than the back of the prescriptions," Mr. Parrado replied: "I've never seen it documented anywhere other than that." *Id.*

However, Mr. Parrado subsequently acknowledged that resolution of a red flag could be documented other than on the back of a prescription. *Id.* at 136. And he later agreed with Respondent's counsel that if a patient had been a regular and long standing patient of the pharmacy, it would not be "necessary to do the full-blown documentation that you would do on the first prescription once you've resolved the red flag." *Id.* at 177. However, he maintained that some notation should still be made on the prescription so that if the prescription was questioned by a regulatory agency, there would be some evidence to defend the dispensing decision. *Id.; see also id.* at 190. Mr. Parrado also acknowledged that "some pharmacists document [the] resolution of red flags so that it is . . . available to help their colleagues who [are] filling in for them." *Id.* at 191.

Mr. Parrado rejected, however, the suggestion of Respondent's counsel that documentation need not be placed on the prescription because "there's no way for the floater pharmacist . . . who takes over to actually go through [the prescription file] and know where those [notes] are because they're all written on the back of prescriptions." *Id.* at 192. As Mr. Parrado explained, the pharmacist would see the prescription number when he looked up the patient's profile on the computer, and "it would be very easy to go pull that prescription out of the file." *Id.* Then asked how a pharmacist would know which prescription to pull if the patient had been filling the prescription every month for ten years, Mr. Parrado testified: "That's why you would have documented this as a regular patient. You would have done something on that scrip[t]." *Id.* at 192. However, he then acknowledged that notes generally can be made in the pharmacy's dispensing software. *Id.* at 193.

Mr. Parrado acknowledged that a patient who has been on opiates for a significant time and who has developed tolerance may need to exceed the manufacturer's daily recommended dosage. *Id.* at 137. He acknowledged that the dosing depends on "the specifics" of the patient's condition. *Id.* He also agreed that having a patient on a narcotic contract so that the patient only obtains narcotics from a single clinic could be helpful in resolving red flags. *Id.* at 137–38. He further agreed that if the narcotic contract "called for routine urine screens to ensure that the patient was actually taking the drug," that would "be helpful" in "prevent[ing] diversion." *Id.* at 138.

Asked if he had reviewed PMP data to determine the drug history of any of the patient, Mr. Parrado said that he had not and that the law did not allow him to. *Id.* While he testified that he looked at thousands of prescriptions from Respondent which covered more than two years, DEA did not give him noncontrolled prescriptions and he looked only at the schedule II prescriptions. *Id.* Given this, Respondent's counsel later asked Mr. Parrado if he had "no way of knowing what . . . adjunct drug therapies . . . any of these patients were taking?" *Id.* at 160. Mr. Parrado answered:

> Well, only because of what I saw in the Respondent's exhibits where there were some partial medical records that did have all the drugs the patient was taking on a very few cases, and on those it was the same on every one of them, the same group, same combination.

Id.

Mr. Parrado acknowledged that Florida law (Fla. Stat. § 893.04(2)(a)) states that a pharmacist may dispense a controlled substance in the exercise of his professional judgment when the pharmacist or pharmacist's agent has obtained satisfactory patient information from the patient or the patients' agent. Tr. 139. After Respondent's counsel pointed that this provision does not require that the pharmacist alone talk to the physician alone and allows a pharmacist to talk to the patient or the patient's agent, Mr. Parrado testified that "it says in [Fla. Admin. Code r.] 64B16–27.831 that when you have a concern you shall contact the prescriber." *Id.* at 139–40.

Turning to J.A., the patient who had received prescriptions for Adderall and Dilaudid, Mr. Parrado conceded that while opiates "have a respiratory depressant effect," they are not categorized as depressants under the Controlled Substances Act. *Id.* at 141–42. He also acknowledged that when a drug has a shortage and its wholesale price rises, the retail price would also rise. *Id.* When then asked whether it is standard practice to input the average wholesale price of a drug into a pharmacy's dispensing software and that the software has algorithms that actually generate the retail price, Mr. Parrado explained that "[t]here are different ways to fix that algorithm" and that he had sometimes overridden the price set by the software. *Id.* at 143. While Mr. Parrado acknowledged that, in 2008 and 2009, two major oxycodone manufacturers had recalled their products resulting in shortages and that wholesalers would take advantage of this and charge higher prices, he disagreed with the suggestion that "those shortages continued and had ripple effects throughout Florida well into 2010 and 2011." *Id.* at 144. Rather, he testified that the shortages did not have "that much" of an effect and "[o]nce it became available again the prices were not that far skewed"[17] *Id.*

While Mr. Parrado acknowledged that he did not go to the pharmacy closest to his home because he knows the pharmacist at the pharmacy he goes to, he explained that "[m]ost people go to a pharmacy for . . . some sort of a convenience, or a reason, and he [the patient] had to have a reason to go to that pharmacy. That's what I would want to know. That's what I would want to document.'' *Id.* at 146. Asked if he documented on the back of every controlled substance prescription the reason a patient had driven 10 or 15 miles on roads with stop lights to get to his pharmacy, Mr. Parrado answered: ''No, of course not.'' *Id.* at 148. However, he then adhered to his position that ''[s]tandard practice is if you have the red flag to document it.'' *Id.* As for whether it would be a red flag if the patient ''lives 20 or 30 miles away and [has] seen a doctor who's in close proximity to the pharmacy'' and ''[t]hat red flag then is resolved?''; Mr. Parrado testified that ''I'd still want to know the address. There's going to be multiple red flags here.'' *Id.* at 148–49. On a further question regarding ''the red flag of someone driving 10 or 15 miles'' and ''[i]f the physician happens to be in close proximity to the pharmacy, that resolves the red flag, doesn't it?''; Mr. Parrado testified: ''Not necessarily'' and explained that: ''[i]t's not just one thing. It's multiple things. That's the combination of red flags.'' *Id.* at 149.

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[17] By contrast, Mr. George testified that from 2010 through 2012, the wholesale "price sometimes went three times to 10 times more." Tr. 538–39.

Mr. Parrado testified that the drugs themselves (hydromorphone and oxycodone 30) raised a red flag as they are known drugs of abuse. *Id.* at 149–50. While Mr. Parrado acknowledged that he had filled prescriptions for oxycodone 30, he could not ''remember ever filling a prescription for hydromorphone.'' *Id.* at 150. However, when asked what he would document on a prescription when he was practicing and was presented with a prescription for oxycodone 30 but there were no other red flags, Mr. Parrado testified: ''[n]othing because it wasn't a red flag.'' *Id.* at 151; *see also id.* at 166.

Asked the same question with respect to hydromorphone, Mr. Parrado answered: ''Well, you know, there again, looking at the dose, I would have to look at the patient profile, see if the patient has developed a tolerance to that drug, and at that point the red flag—there's nothing to write down because there isn't a red flag.'' *Id.*at 151. Later, on cross-examination, Mr. Parrado acknowledged that his review of the prescriptions did not include any information that would have allowed him to determine whether the patients had been on narcotics for a significant period and developed tolerance as he reviewed only what DEA gave him. *Id.* at 161–62. He also acknowledged that neither the prescription nor the prescription label ''tells you anything about the patient [sic] history.'' *Id.* at 177.

Turning to the red flag of pattern prescribing, Mr. Parrado acknowledged that if a physician prescribed different narcotics for different patients, sometimes wrote for extended release drugs and other times immediate release drugs, and varied the strength of the drugs, this would not be pattern prescribing. Tr. 153. Mr. Parrado then agreed that the same would hold true for the clinic itself. *Id.* And he subsequently acknowledged that pain management is a legitimate medical practice, which often times requires the prescribing of opioids in significant quantities as patients develop tolerance. *Id.* at 154.

As for the red flag of therapeutic duplication, Mr. Parrado agreed that extended release drugs ''were expensive'' even though ''[t]here were some generics available'' during the time period at issue and that a patient who lacked insurance ''would have difficulty paying for an extended release oxycodone product.'' *Id.* at 155–56. Mr. Parrado then acknowledged that if a patient required oxycodone 30 for his ''normal pain,'' the physician would not be acting illegally if he prescribed a lower strength drug for the patient's ''breakthrough pain.'' *Id.* at 156.

Turning to the methadone prescription which Respondent filled for B.W. (GX 14, at 3) (on the same day it also filled a Dilaudid prescription for him), Mr. Parrado conceded that he did not have any evidence that B.W. had overdosed, abused the drug, or sold it on the street. Tr. 158–59. Mr. Parrado then acknowledged that he had no evidence that any of the prescriptions were abused or sold on the street. *Id.* at 159.

Asked whether his concern about methadone-related overdoses was a general concern or a specific concern related to B.W., Mr. Parrado testified:

> That was a concern that I would have wanted to have seen a red flag resolved. Why is he on hydromorphone and methadone both, which are both immediate release . . . you know, you don't use two immediate release opioids for breakthrough pain. You use a long acting as a base and then the immediate release for breakthrough.

Id. Later, on cross examination, Mr. Parrado explained that the problem with using methadone for pain management ''is that the pain relief you get . . . probably peaks at about three to four hours and tapers off rather quickly after that, but the respiratory depressant part . . . continues to grow even after the pain relief has gone down, so people are apt to take another pill,'' thus increasing the respiratory depressant effect. *Id.* at 174. However, Mr. Parrado acknowledged that methadone may be appropriate for certain patients. *Id.*

Mr. Parrado then agreed with Respondent's counsel that ''it's not common, but it's not completely unheard of for individuals who may not have insurance or may have allergies or other reasons why certain long-acting drugs do not work'' [18] *Id.* at 159–60. And he also agreed with Respondent's counsel that because of genetic differences, some persons may metabolize certain opiates in a more effective manner than others. *Id.*

Mr. Parrado further acknowledged that the DEA Pharmacist's Manual does not use the term red flag and does not specifically tell pharmacists how to identify red flags. *Id.* at 163. However, he then testified that the ''[M]anual gives you a lot of information that you have to use your professional judgment . . . . It's not going to list line by line, but that's why you have pharmacists exercising professional judgment.'' *Id.* Mr. Parrado further testified that a pharmacist ''should be able to defend that professional judgment.'' *Id.*

After acknowledging that neither the CSA nor DEA regulations use the term ''red flags,'' as well as that the CSA and DEA regulations do not ''talk about distances from patients,'' Mr. Parrado agreed that ''there is no bright line that . . . if it's beyond a certain distance, it's always wrong.'' *Id.* at 164. However, Mr. Parrado subsequently testified that if patient lived more than 40 miles from the doctor's office, that would be ''one of the red flags for diversion.'' *Id.* at 208.

As for whether family members seeing the same doctor ''makes the doctor's prescriptions for those family members invalid,'' Mr. Parrado testified that ''[i]t raises a question. It may not make it invalid.'' *Id.* at 164. Mr. Parrado then explained that ''I have to validate—I have to verify the validity of that script.'' *Id.* at 165. While Mr. Parrado acknowledged that a pharmacist could ''possibly'' resolve the red flags created by the circumstances of two people in the same household ''need[ing] the exact same drug and pay[ing] those large quantities of money,'' he rejected the suggestion of Respondent's counsel that this could legitimately occur where ''family members . . . live together, didn't have insurance'' and had to ''pay out of pocket.'' *Id.* Mr. Parrado then testified: ''You can buy a lot of insurance for $2,700'' and that the costs of the prescriptions would be a red flag that he "could not have resolved." *Id.*

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[18] Mr. Parrado subsequently acknowledged that extended release opioids could be problematic for patients who have had bariatric surgery. Tr. 175. Also, on questioning by the ALJ, he testified that if a patient was allergic to a medication, ''you wouldn't be filling'' that prescription. *Id.* at 213.

Mr. Parrado further acknowledged that in evaluating whether a pharmacist had complied with the standards of practice in dispensing a prescription, "it would be helpful" to know various information. *Id.* at 177. These include "what the pharmacist knew" about: (1) The patient, including his/her medical condition, history, diagnosis, cause of the pain and drug utilization; (2) the prescribing physician, including his/her specialty, board certifications, practice location, and reputation; and (3) the drug being prescribed . *Id.* at 178; *see also id.* at 202–03.

Asked if he was aware that one of the physicians who issued the prescriptions he had testified about "is a noted anesthesiologist," Mr. Parrado testified that "if it doesn't say it on the prescriptions itself, I wouldn't know it." *Id.* at 183–84. Then asked by Respondent if he knew "that that particular noted anesthesiologist was a physician at a major regional hospital before being involved in the practice of pain management care," Mr. Parrado answered: "[n]o, I would not have known that." *Id.* at 184. Mr. Parrado also testified to the effect that the fact that the physicians (with the exception of one who had since died) who practiced at 24th Century have had their registrations renewed would not change his opinion. *Id.* at 186.

Mr. Parrado further acknowledged that the issue of prescribers not placing the patient's address on prescriptions has become "very common," but that the pharmacist has to verify the patient's address. *Id.* at 193. He also testified that in 2008, DEA sent a letter to pharmacists which stated that the pharmacist "could add in" the patient's address. *Id.* at 194. Mr. Parrado then agreed that if the prescription was only missing the patient's address, this does not raise "a concern about diversion." *Id.* at 195. Subsequently, the Government identified several prescriptions where the patient's address had not been placed on the front of the prescription. *Id.* at 206 (discussing GX 13, at 3, 5, 21, 27, and 29). However, in each instance, the patient's address was on the dispensing label which was affixed to the back of the prescription.[19] *See id.* at 4, 6, 22, 28, and 30.

While Mr. Parrado continued practicing through 2012, he could not remember the pharmacies he worked at having ever filled prescriptions written by a doctor at the 24th Century clinic. *Id.* at 195–96. While Mr. Parrado acknowledged filling prescriptions that came from the Kenaday Clinic (*see* GX 14, at 7–10), he testified that "[o]n the ones I filled, I called and checked them very carefully." Tr. 196–97. Asked what he did to resolve the red flags, Mr. Parrado testified that there was an issue of dosing and whether "the patient had developed a tolerance for that dose," and that he called the doctor.[20] *Id.* Mr. Parrado added that he had spoken to the doctor twice, after which he "wouldn't fill anymore." *Id.* at 199.

Asked whether there were other concerns besides the dosing with the prescriptions written by the Kenaday doctor, Mr. Parrado testified that another prescription presented a distance concern and he did not fill the prescription and gave it back to the patient. *Id.* Subsequently, Mr. Parrado then acknowledged that the prescription that presented the dosing issue may also have presented another issue, that being that the doctor had prescribed "a combination of hydrocodone, Xanax, [and] Soma." *Id.*at 200. Mr. Parrado testified that after talking to the physician and believing that the prescriptions had a legitimate medical purpose, "after that I didn't feel comfortable anymore and after speaking with the doctor a couple more times I decided I could not take his word for the validity and I wouldn't fill them anymore." *Id.* at 201. As Mr. Parrado further testified, "[o]nce I saw the pattern of prescribing coming from that clinic is when I stopped." *Id.* at 202.

Finally, Mr. Parrado acknowledged that a doctor can issue a prescription for a legitimate medical purpose and the patient may nonetheless misuse it or sell it on the street, but that this does not make the prescription invalid. *Id.* at 204. Nor does a patient's misuse or selling of the drug to another make a pharmacist's decision to dispense the prescription wrong unless the pharmacist knew or should have known that the patient was going to misuse or sell the drug. *Id.* at 205.

Respondent's PIC's Testimony

As noted above, Respondent's Expert Mr. Badawi did not address any of the prescriptions which the Government submitted into evidence. Kasey George, Respondent's PIC, did offer testimony as to why some of the prescriptions were dispensed.

Mr. George testified that he has been a pharmacist for 21 years, that he has 12 to 13 years of experience in retail pharmacy, and that he has been Respondent's PIC for seven years. Tr. 445–46. Mr. George holds an active pharmacist's license in Florida and holds inactive licenses in three other States. *Id.* at 446. He testified that he does not have either a criminal history or a disciplinary history on his pharmacy license. *Id.* at 445. He also testified that he had obtained his pharmacy degree from Temple University in 1994, that he had taken continuing education classes, and that he had attended a class on dispensing controlled substances in 2013 at which Mr. Parrado had spoken. *Id.* at 447–48.

Mr. George testified that he is the only full-time pharmacist at Respondent, which is open six days a week, and that if he has a day off, he schedules a temporary pharmacist to work that day. *Id.* at 448. Respondent's counsel then asked what controlled substance dispensing protocols were in place at Respondent from 2011 through February 2013, when the Administrative Inspection Warrant was served. *Id.* at 448–49. According to Mr. George, the protocol:

> involves many things, including first we have check [sic] that the doctor's office is located within 20 miles from the pharmacy. Then we check the patient's ID, Florida ID, and make sure that the patient has a Florida ID. The next step we do is we check the prescribing physician's address and their phone number, and we check in the publicly listed Web site to see that it matches what's printed on the prescription. Then we check that the doctor has a valid DEA license active and also an active NPI number.
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> * * * * *
>
> . . . And we check the—call the doctor's office and get the diagnosis for the condition treated. And also we ask for the diagnosis studies they have done and make sure that the studies are consistent with the medical condition that is being treated and also the prescription. . . . And we ask for all the records to be sent to the pharmacy, and we check that they have the narcotic contract with the patient. . . . And also we ask for the urine drug test result and those records. Then we are not done with that.
>
> And we have to check the patient's ID, which is present with the DMV Web site to

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[19] Asked by Respondent's counsel if "Florida law says there shall appear on the face of the prescription or written record thereof" and thus allows for the patient's address to be placed on the back, Mr. Parrado testified: "[t]hat law was changed. At the time these prescriptions were written, that law did not say on the prescription record thereof. . . . It just said it had to be on the face of the prescription." Tr. 209. According to the 2011 Florida statutes, Section 893.04(c) stated that "[t]here shall appear on the face of the prescription or written record thereof for the controlled substance . . . [t]he full name and address of the person for whom . . . the controlled substance is prescribed." Fla Stat. Ann. § 893.04(c) (2011). Contrary to Mr. Parrado's testimony, the statute had the same wording throughout the relevant time period.

[20] At this point the Government objected that the question was "beyond the scope of direct examination." Tr. 197. Respondent's counsel replied that the question went to Mr. Parrado's credibility, and the ALJ overruled the objection. *Id.* at 198.

> see that address is correct. Then . . . end of 2011, PDMP came. From that day onwards, we check for every new patient, and every time they come we have to check the PDMP to see any doctor shopping or any early filling and check also . . . the patient's credibility because if their [sic] address is available there. And after that, all that pharmacist's professional judgment also comes into that protocol.

Id. at 449–51.

Mr. George testified that he reviewed the prescriptions submitted by the Government and he acknowledged that he was the dispensing pharmacist on "the vast majority of" them. *Id.* at 451. He testified that he had used the above protocol in dispensing the prescriptions. *Id.* He then denied that he was required to fill prescriptions that originated at certain clinics or that were presented by certain patients. *Id.*

Mr. George testified that he was "required to document every conversation with a patient or physician if the conversation was about concern related to" a controlled substance prescription. *Id.* at 451–52. Asked by Respondent's counsel "where was that documented?"; Mr. George testified: "[w]e have a two-page pharmacist's due diligence checklist separately filed in a binder in an A to Z format according to patient's last name, and all the documents pertaining to that patient's prescription is [sic] attached to that in the file." *Id.* at 452. Mr. George further testified that he had used the due diligence forms for the patients whose prescriptions were at issue in this case. *Id.* Mr. George then testified that when DEA executed the AIW, they did not ask him to provide the due diligence forms and did not take them. *Id.* Nor did they ask him to provide documentation showing that he had made inquiries and resolved red flags. *Id.* at 452–53.

Asked by Respondent's counsel where he would "document the resolution of questions about" a controlled substance prescription, Mr. George answered:

> It used to be if it is one or two items you used to document on the face of the prescription. Since the information needed to prevent the abuse and misuse and diversion, a lot of documents [sic] involved, if I decided to go extra step to get all the available documents filed in a separate sheet and document a pharmacist's checklist so I can do beyond the required, more than the required and go and fill in in vast places.

Id. at 455–56. Noting his testimony that he had formerly documented the resolution of such questions on the back of the prescription, Respondent's counsel asked Mr. George when he changed to using checklists and obtaining the records he described. *Id.* at 456. Mr. George testified that it was "[f]rom 2010 onwards." *Id.* at 457.

Mr. George then explained that his protocol also included interviewing the patients to "ask them their conditions and why they're being [sic] taken [sic] these prescriptions." *Id.* Mr. George further asserted that "in that interview, I can find out what is the real need and also if they have any intention to abuse or misuse or any diversion involved in that scheme." *Id.* at 458.

Mr. George testified that "we verify . . . the credibility of the doctors through the paperwork and the documents." *Id.* He further stated that "I visit the doctor's office and the clinic occasionally and get to know the doctors," and "I talk personally to the doctors and also make sure that they have a protocol in place, which I also make sure that that is inconsistent of our protocol." *Id.* Continuing, Mr. George testified that "I make sure that all that paper which I mentioned, narcotic contract and opiate contract, all are in place." *Id.*

Mr. George acknowledged that he was familiar with the physicians who wrote the prescriptions at issue, and that most of them worked for 24th Century, which "is a pain management clinic." *Id.* at 459. Asked by Respondent's counsel what he knows about the specialties and certifications of 24th Century's doctors, Mr. George answered:

> One doctor, he is no more. He's [sic] passed away three or four years ago. He was the director of this clinic, and he was the chief anesthesiologist in [sic] Tampa General Hospital. He was a famous doctor, and his expertise was a big asset at clinic, and many patients liked him.

Id. Subsequently, Mr. George testified that the name of this doctor was Cornelius Ruperto. *Id.* at 466.

Notably, Dr. Ruperto did not write any of the prescriptions at issue in this matter. *See generally* GXs 3, 13, 14, and 15. Moreover, his name is not listed on any of the prescription forms. *See generally* GXs 3, 13, 14, and 15. This is for good reason, as according to Dr. Ruperto's online obituary of which I take official notice,[21] Dr. Ruperto died on December 8, 2008, more than two years before the earliest prescription in evidence. And of further note, Mr. George offered no testimony regarding the specialties or board certifications of the doctors who actually wrote the prescriptions at issue in this matter.

Asked by Respondent's counsel how he resolved the red flag of multiple patients presenting similar narcotic prescriptions which were written by the same doctor, Mr. George acknowledged that "[i]f I see that a doctor is writing a certain medication and the same quantity and same way to every patient, then it is a red flag to me." *Id.* at 467. Continuing, Mr. George explained: "[b]ut . . . when I see that doctor write the medications, but in different doses and different quantity . . . it's different, and they write different medication along with it, and their treatment plan is different, then after my due diligence is being done, I feel comfortable filling that prescription." *Id.* Mr. George subsequently testified that the 24th Century doctors prescribed oxycodone in both 15 and 30 mg dosages, methadone in 5 and 10 mg dosages, morphine in 30, 60 and 100 mg dosages, hydromorphone in 4 and 8 mg dosages, and sometimes Opana. *Id.* at 475–76.

Next, Respondent's counsel asked Mr. George about the oxycodone 30 prescriptions whose labels bear sequential RX Numbers and which were dispensed on August 4, 2011 to J.P. and T.P., who have the same last name and had travelled from Saint Augustine (196 miles). GX 3, at 2–3. Mr. George asserted that "I remember that case in detail" and that J.P. and T.P. were husband and wife and that T.P. had a bulged disc from a 1998 accident and "was our patient from 2009." Tr. 468. He also asserted that J.P. had "a motor vehicle accident" and "had problems with his neck and . . . back." *Id.* at 468–69. Mr. George did not explain when J.P.'s accident had occurred or how long he had been Respondent's patient. *See id.* While Mr. George asserted that he filled the prescriptions, because "after doing all the due diligence and following the protocols, talking to the doctors, I was comfortable within my professional judgment to fill that prescription," *id.*, Respondent produced no evidence to corroborate his testimony, not even the two-page due diligence checklists. Of consequence, the ALJ did not find Mr. George's testimony credible as to the actions he took to resolve the red flags presented by J.P.'s and T.P.'s prescriptions.[22] R.D. 48.

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[21] *See www.legacy.com/obituaries/tbo/obituary.aspx?n=cornelio-aquino-ruperto&pid=121231660.* Respondent may dispute my finding by filing a properly supported motion no later than 15 calendar days from the date this Order is mailed.

[22] Mr. George further testified that in 2012, "J.P. was filling the prescription in the pharmacy, and when I called the doctor's office, I found that J.P. had an admission" to a hospital in St. Augustine. *Id.* at 469–70. According to Mr. George, the doctor then requested the records from the hospital in St. Augustine; the records showed that J.P. "was positive for his oxycodone and Valium he was on," as well as cocaine. *Id.* at 470. According to Mr. George, J.P. was then discharged from the clinic for breaching his contract and he decided to stop filling prescriptions for him. *Id.* Mr. George did not explain, however, why J.P. had the prescription he was attempting to fill if he had been discharged from 24th Century.

Mr. George also acknowledged that a prescription that exceeds the manufacturer's recommended daily dosage presents a red flag. Tr. 470. Mr. George testified that the prescription "does not say the whole story" and when the patient's dose is above the manufacturer's recommended dose, the pharmacist "ha[s] to go and look at the patient's profile and profile history to make sure why this patient is taking higher doses." *Id.* at 471. Mr. George further testified that "everybody know [sic] that tolerance plays a big role in the doses prescribed" and that "there is no ceiling doses for opiates." *Id.* Mr. George then testified that when a prescription is for a higher dose than the recommended dose, "the pharmacist's duty is to call the physician and check with them . . . and go through [the] profile and see how long [the patient's] been on that medication and . . . learn how much the tolerance is." *Id.* Mr. George then maintained that when he filled prescriptions that exceeded the maximum recommended dosage, he did all of these steps "and I write my notes on my due diligence checklist why I did it." *Id.* at 472.

Addressing the prescriptions that were missing patient addresses, Mr. George testified that the former head of the Office of Diversion Control had published a memo which "says that if the pharmacist has to make any changes in C2 prescriptions, they have to follow state laws and guidelines." Tr. 472. Mr. George then noted that Florida law "clearly says that [the address] shall be on the face of the prescription or the written record thereof," and added that he would "verify the patient's address though the DMV Web site[] [a]nd also check the PDMP" and use the prescription label to provide the address. *Id.* at 472–73.

As for the instances in which patients presented prescriptions for two short-acting opiates, Mr. George testified that "there are many reasons" that "doctors write two prescriptions," including that "the patient is allergic to certain medications," "has intolerance for the drug," may have had "gastric bypass surgery," or be a "dialysis patient." *Id.* at 474. However, Mr. George testified that "[n]ormally doctors write the long-acting medication along with the short-acting." *Id.*

As for how he resolved the red flag, Mr. George testified that "you . . . study the situations [sic] and what is the condition of the patient through talking to the doctors and talking to the patients and checking their profiles [and] history." *Id.* Asked by Respondent's counsel if those are "actual examples of things that occurred where you got information like that from patients who filled prescriptions," Mr. George answered: "Yeah. We will get information. That's the case." *Id.* at 474–75. Mr. George did not, however, offer any testimony identifying the specific conditions of those patients who presented two prescriptions for short-acting narcotics which were filled by Respondent.

Mr. George further testified that he obtained medical records from the 24th Century clinic. *Id.* at 477. Respondent's counsel then asked Mr. George if he had "seen Respondent's Exhibit 3 before today?" *Id.* at 479. Mr. George answered "yeah," and added that "it is actually from one of the copies which I get from the clinic"; he then testified that these records "were maintained at" Respondent and that the records were present when DEA executed the AIW. *Id.* Mr. George also testified that the Exhibit contained an accurate representation of the records Respondent maintained on three of its patients, K.D. (pages 1 through 17); S.D. (pages 18 through 33); and H.C., Jr. (pages 34 through 51). Tr. 480, 482. Notably, the records contained such items as driver's license verifications, radiology reports, progress notes, and opioid contracts. *See generally* RX 3.

On *voir dire,* the Government asked Mr. George how he received the records from the clinic. Tr. 490–91. Mr. George answered: "sometimes it is in a block of a—I send my technician to get it because patients are waiting in my—I go and ask them to get the copy and get it to me so I can verify it before filling it." *Id.* at 491. Mr. George subsequently testified that Respondent's Exhibit 3 was "a representative sample of the type of record [he] got for hundreds of patients [of his] pharmacy." *Id.* at 498.

Asked by Respondent's counsel "what, if any information on pages 20 through 29 . . . was important to [him] at the time" he was deciding to fill controlled substance prescriptions for S.D., Mr. George testified that the records told him "what the diagnosis is, why this patient [is] being treated for the medication they [sic] are [sic] prescribed." *Id.* at 480–81. He further asserted that he looked at the progress notes (RX 3, at 29) to "see any changes in there," as well as page 30, which told him that "the patient has [an] opiate contract there." *Id.* at 481.

Mr. George then testified that he looked at these records as "an extra step to prevent the abuse and misuse of the controlled substances." *Id.* Asked whether his training as a pharmacist gives him "the ability to understand certain things within the medical record as far as the diagnosis and the condition of the patient," Mr. George testified that "[t]hrough experience, I learned to look through these forms and understand it [sic]." *Id.* Mr. George then testified that the records included indications of conditions that would cause pain. *Id.* at 481–82.

Asked whether there was information on page 44 (a December 6, 2012 Visit Note for H.C., Jr.) that would allow a layperson and pharmacist "to determine what condition the patient was being treated for," Mr. George answered "yes." *Id.* at 482. Asked if "the information contained in these medical records [is] consistent with the patient having pain and needing a controlled substance prescription from a pharmacist's perspective?", Mr. George again answered "yes." *Id.* at 482–83.

Next, Mr. George was asked about the prescription (GX 3, at 1) Respondent dispensed on July 28, 2011 to T.V., who lived in Pensacola—472 miles from Respondent—for 210 tablets of oxycodone 30. Tr. 493. Mr. George testified that she had been his patient "since 2009," and that in deciding to fill her prescription, he had had done "all my due diligence, checked with the doctors, checked all the medical records [he] could" and "interviewed the patient." *Id.* at 494. Mr. George further testified that "when this patient came in the counseling and when I was talking . . . [the] patient knew that distance is a very fact that pharmacist may not fill it." *Id.* According to Mr. George, T.V. said she had gone "through four back surgeries" and had tried "interventional pain injections" which "failed." *Id.* Mr. George then testified that T.V. "lifted her shirt and said, look at my back, and I looked that there were four scars" and T.V. "mentioned that there were rods and plates placed here." *Id.* at 495. Mr. George thus maintained that "even though the distance was far, through my experience and the need of the patients [sic], it made me come to a conclusion that this patient, I will fill the prescriptions." *Id.*

While on cross-examination, Mr. George testified that another pharmacist had filled this specific prescription, *id.* at 578–79, he reiterated his earlier testimony that T.V. had "been coming from 2009 onwards." *Id.* at 579. He then added that "I know this patient very well, and I have a very well written record on this patient." *Id.*

After again stating that he did not fill the prescription, Mr. George testified that "every pharmacist who worked in that Hills Pharmacy have [sic] that file. That's the reason the due diligence paper is filed separately." *Id.* at 579–80. Mr. George then testified that "[w]hen this patient comes again, that pharmacist has the opportunity to go and look at why this patient's prescription was filled last month" and ask "[i]s there any reason, or should I reject this?" *Id.* at 580. Continuing, Mr. George testified: "[w]hen they [sic] see other pharmacist, especially my notes, saying that all the due diligence were [sic] done and all the red flags were resolved, that pharmacist will be comfortable looking at. And they will probably call the doctors, I don't know [sic] he called or not. But that is his duty to call the doctor and verify." *Id.* Mr. George again reiterated that this documentation was written down "[i]n my due diligence sheet" which is "in the pharmacy." *Id.; see also id.* at 551 (Mr. George's testimony that the due diligence forms are in a binder which is "[s]till in the pharmacy.").

Subsequently, the ALJ asked Mr. George if he recalled why T.V. "travelled from Pensacola to Hills Pharmacy?" *Id.* at 588. After answering "yes," Mr. George testified:

> This patient had multiple surgeries done in Tampa General Hospital and that time the doctor, the chief anesthesiologist was Dr. Cornelio Ruperto, and he become [sic] the director of the clinic where this prescription was written. So she used to come *and see that doctor always.* And while I was interviewing that patient she said she likes the doctor and she wanted to continue seeing that doctor. That's why she was coming from that 450 miles.

Id. (emphasis added).

Respondent's counsel then asked Mr. George about the back side of two prescriptions for 180 oxycodone 30 (GX 3, at 35) which cost $1350 each and were written for H.C., Sr., and H.C., Jr.; the latter is the same person whose records are found at pages 34 through 51 of Respondent's Exhibit 3. Tr. 495–96. Asked to explain what inquiry he made to learn about him and his condition, Mr. George testified:

> [W]hen I got this prescription, I did all my due diligence and followed my protocols. Then I looked—he has a bulging disc, and I filled this prescription. He is coming in my pharmacy from 2009 onwards. And when he came to pharmacy with all these conditions, he'd been filling for [sic] insurance—he had insurance coverage that time. Then that time he was paying $35, was the copay. So he'd been paying that from 2009 'till end . . . of 2010.
>
> Then he left the pharmacy. Then two years he did not come to the pharmacy. Then in 2012, he came back to the pharmacy with a prescription, and he did not have insurance, which Hills Pharmacy always ask when he was in where is your insurance, and he said he lost the insurance. He didn't have any insurance coverage.
>
> Then he said that I need this medication, I'm on this medication. And he brought a profile also where he was. And I don't remember that it is a—and he showed me he was taking this medication. So he said he's willing to pay whatever the cash price at that time. And I filled this prescription for cash.

Id. at 496–97. Mr. George then testified that H.C., Jr.'s drug therapy had not changed from when he had insurance. *Id.* at 497. Mr. George did not, however, offer any testimony regarding his decision to also dispense oxycodone 30 to H.C., Sr.

Mr. George subsequently testified that he had no knowledge that any of the patients who received the prescriptions at issue abused or diverted the drugs he dispensed to them. *Id.* at 498. Respondent's counsel then asked him "how do you respond to the allegations . . . that you filled prescriptions that had red flags on them?" *Id.* at 498–99. Mr. George testified:

> From 2013 onwards, I modified my protocol and changed it to print out patients' residence to less than 15 miles, and also in our protocol changes that we only fill the doses consistent with the manufacturer's recommended doses, and also we will not fill for patient for the controlled substances who reside in the same addresses. So after making that [sic] changes, if it—today I will—that red flag will be considered in a different way and say that this is not according to my protocol, so I will not be comfortable.
>
> That doesn't mean that what I did before that was not written for legitimate medical purpose, but at this point, because my protocol is more stringent and more strong, in my effort to prevent the misuse and abuse and diversion, I will check one more time.

Id. at 499–500.[23] Mr. George then testified that as of February 19, 2015 (three weeks before the hearing), Respondent "completely stopped" filling controlled substance prescriptions "issued from any pain management clinic." *Id.* at 500. Asked why he had made this change, Mr. George testified that "I know we all have a part to do to prevent the abuse and misuse and diversion of the controlled substances. As a professional provider, and the Government—DEA is trying to prevent that. And as a professional provider, I also have a responsibility for that." *Id.* at 500–01. He then added that part of the reason he had changed his policies was because "always there are bad apples everywhere" and "I know that I'm less than the perfect." *Id.* at 501. Mr. George then testified that he had "never" filled a controlled substance prescription having "knowledge that it was not issued for a legitimate medical purpose." *Id.* at 502.

Next, Mr. George testified regarding a chart he had created which shows from January 1, 2011 through November 30, 2014, the total prescriptions dispensed by Respondent during each year (except for 2014), the total non-controlled and schedule II prescriptions dispensed, and the total schedule III through V prescriptions dispensed. RX 2, at 1. Notably, the chart does not provide any data for the schedule II prescriptions alone, and instead adds them to the non-controlled prescriptions. *See id.* The chart also purports to show the percentage of Respondent's total dispensings comprised by schedule III through V drugs, the "percentage change from previous year" and the "percentage change from 2011." *Id.* While five of the six entries in the latter two columns show percentage reductions, the chart does not state whether the percentage change is in the total schedule III through Vs dispensings or in the percentage of total dispensings comprised by schedule III through V drugs. Moreover, the 2014 figures do not include data for the month of December.

Another chart shows data for Schedule II through V for the years 2011 through 2013 and for 2014 through November 30. RX 2, at 3. The chart reflects a decrease in the total number of controlled substance prescriptions dispensed and a decrease in the percentage of total dispensings comprised by schedule II through V dispensings. *See id.*

Subsequently, Mr. George answered "yes" when asked by Respondent's counsel: "[d]o you accept responsibility for the fact that you filled prescriptions for controlled substances that had red flags on them?" Tr. 507. However, when then asked if he had "ever knowingly ignored your duties as a pharmacist to exercise your professional judgment?", Mr. George answered: "No, I never did." *Id.* at 507–08. Mr. George further testified that "even though I did my best, our best to control that and prevent the abuse and misuse, that is not perfect. It is always less than perfect. Human beings are not perfect. I accept that responsibility." *Id.* at 539–40.

On cross-examination, Mr. George acknowledged that a prescription which calls for the dispensing of "a high quantity" of a controlled substance presents a red flag as do "patients coming from long distance." *Id.* at 552. However, he then maintained that he had resolved all the red flags and had documented this on the due diligence checklists which were in the binder "in the pharmacy." *Id.* He further testified that he would consult the medical records he obtained before dispensing controlled substances. *Id.* at 553. Asked by the Government if he "understand[s] medical records," Mr. George testified:

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[23] On cross-examination, however, Mr. George was asked if a patient's address being 63 miles from Tampa presented a red flag. Tr. 570. Mr. George testified:

> Sixty-three miles, this time, yes, I will not fill that 63 miles, above 50 miles because my protocol has changed after the administrative warrant then to less than 50 miles. But at that time then when I filled it, it was a red flag, but I did my due diligence and followed the protocol, so that time it was okay in that I resolved that red flag.

Id. at 570–71.

> I don't understand it the way the doctors are trained to understand. By experience, I look whether this prescription was issued for a legitimate medical reason. This is not my duty as a pharmacist. I would do something above and beyond in order to support the effort to prevent abuse and misuse. It is not part of my duty to read the medical report. I am doing an extra step for myself and to serve the community.

Id. at 554–55.

The Government then asked Mr. George about Respondent's dispensing of 240 oxycodone 30 tablets to K.D., on April 21, 2011, pursuant to a prescription issued by Dr. S.A.-H. of the 24th Century Clinic (GX 3, at 20); K.D. is one of the patients whose partial records were submitted into evidence. *See* RX 3, at 1–17. Asked whether he "consult[ed] the medical record that is accompanying this prescription before dispensing that prescription," Mr. George answered: "I didn't say that. I said my medical records are filed in the pharmacy, not with this prescription." Tr. 557. Then asked whether he had dispensed the prescription, Mr. George testified that he did not dispense "[t]hat particular prescription" and that "another pharmacist" had filled the prescription. *Id.* When asked "who would that person be," Mr. George testified that the copy was "very faint" and that could not see "the signature on that page, because the copy is faded." *Id.* I find, however, that the prescription label is readable and bears Mr. George's initials.

The Government then asked Mr. George if he had dispensed the prescription found in the patient file for S.D., who resided in Panama City, Florida. *Id.* at 560. This prescription, which was written on January 19, 2012 by Dr. R.R. of 24th Century clinic, authorized the dispensing of 120 tablets of oxycodone 30. RX 3, at 33. Mr. George acknowledged that he had dispensed the prescription. Tr. 560. He also acknowledged that he had reviewed the partial medical file before dispensing the prescription. *Id.* at 560–61. However, when then asked if he could "tell from this medical record what other controlled substances were dispensed on that particular day," Mr. George testified:

> No. I look only for my prescription which is received in my hand. That is only my concern on that time. Where other places or where the patient got the medication, if I have the PDMP, that will support me on that cause. If I get the medical record, I have no way of saying and understanding where the patient had a different prescription unless I talk to the patient or doctors if he write any other prescriptions. I cannot guess where the prescription was filled for that patient.
>
> And . . . I have one more thing to add on that question. This, as I said, these documents I am looking at, looking [sic] all these documents, above and beyond what the duty required of me because to help. It is not my pharmacist job to read, that is doctor's job. DEA give [sic] license to the doctors and they are well trained in writing these prescriptions, and they have the capacity to look at the patient's record and they are the one who is writing this prescription. I call them—give me a second. I call them, verify them, why they did it, what is the treatment plan, and I look above and beyond what are required of pharmacist. I go all the papers and I make my professional judgment whether this patient can be—this prescription can be dispensed.

Id. at 561–62.

Asked whether he saw a treatment plan in S.D.'s medical record, Mr. George testified:

> In this, all records when you go through the records, there is a medical, the copy of the MRIs and the report from the radiologist and why they are treating it and the notes from the doctor's office, and it say what medication they are writing there, and the doctors notes, the visitation notes there.

Id. at 562.

Then asked whether he looked at S.D.'s MRI, Mr. George testified: "I don't look at MRI. I look at what is the diagnosis in that, whether patient, if it says that a patient has a bulging disc. A couple of the reasons why this medication being prescribed. That's my scope there." Tr. 563. Mr. George then testified that he did look at the MRI report before dispensing the prescription. *Id.*

Mr. George then denied that he was familiar with the term drug cocktail. *Id.* at 563–64. Significantly, the note for S.D.'s January 19, 2012 visit lists multiple drugs that were prescribed by the doctor, including 120 oxycodone 30, MS Contin, Soma (carisoprodol), Xanax, and also included the note of "add Dilaudid 8 mg #120." RX 3, at 29.

S.D.'s patient file also includes a visit note dated June 13, 2012. RX 3, at 24–27. This note states that "Pt. has not taken meds in 5 months" and lists S.D.'s current medications as including five drugs: (1) Carisoprodol 350 mg, one tablet twice daily; (2) Dilaudid 8 mg[24]; (3) MS Contin CR 30 mg, one tablet daily; (4) oxycodone 30 mg, one tablet "every 4–6 hours"; and (5) Xanax 1 mg., one tablet "twice daily." *Id.* at 25. According to the visit note, a drug screen was conducted and S.D. tested negative for opiates. *Id.* at 26. Finally, the visit note lists the prescriptions issued by the physician at this visit; with the exception of Dilaudid, which was discontinued, the prescriptions for carisoprodol, MS Contin, oxycodone 30, and Xanax were re-issued with the previous dosing instructions. *Id.* at 27. However, none of the prescriptions issued to S.D. at this visit are in the record.

Subsequently, the Government asked Mr. George if he had filled the prescription (GX 3, at 16) issued by Dr. P.C. (24th Century) to C.B. of Big Pine Key, which authorized the dispensing of 196 oxycodone 30. Tr. 568–69. Mr. George acknowledged that he had filled the prescription. *Id.* at 569. Asked if he knew where Big Pine Key is, Mr. George stated that he knew that it was in Florida. *Id.* Then asked if he knew how far it was from Respondent, Mr. George testified: "I don't know. It is written in my due diligence list." *Id.* When later asked if he recalled investigating why C.B. had travelled from Big Pine Key to get the prescription, Mr. George answered:

> On this particular patient I don't remember, but I know that when it is more than this distance, definitely I did counsel the patient and record it in the due diligence sheet why they travel. In many cases, I don't remember particularly this patient again. Many cases the reasons are their [sic] spouse are [sic] living in Tampa, they're [sic] in job assignment, or their [sic] doctor is here and they like the doctor. So there are many reasons, but I don't particularly remember. This is from 2011.

Id. at 573.[25]

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[24] No dosing instruction was listed.

[25] To similar effect, the Government asked Mr. George if he knew where Floral City is. Tr. 569. Mr. George answered: "Again, I don't know where the city [sic] located in, but I know it is in Florida." *Id.* After acknowledging that the distance from Floral City to Tampa (63 miles) was a red flag, Mr. George maintained that "I resolved the red flag looking at all the, doing the due diligence and checking with the doctors whether the patient need [sic] the medications and now all the treatment." *Id.* at 571. And asked whether he ever determined why the patient had travelled 63 miles to get the prescription, Mr. George stated that "[o]n most of the patients when I talk to them and interview them and counsel them why they are traveling, and the reasons I get I will put in my due diligence sheet." *Id.* Then asked by the Government "[s]o you don't know the reason right now," Mr. George answered: "right now, because if you said yesterday I would have looked at it." *Id.*

On re-direct, Respondent's counsel, having noted the Government's questions "about remembering specifics about certain patients," asked Mr. George how many patients he had "dispensed controlled substances for in the last five years?" *Id.* at 586. Mr. George testified that "I cannot remember because daily three, four patients comes [sic], in five years,

Continued

The Government's Rebuttal Case

Subsequently, the Government recalled Mr. Parrado to question him about Mr. George's testimony with respect to the medical records in Respondent's Exhibit 3. Tr. 598–99. Mr. Parrado testified that he had "never had medical records in any pharmacy I've ever worked in or managed." *Id.* at 599.

With respect to the medical record for S.D., which, as found above, showed that he had received prescriptions for oxycodone 30, MS Contin, carisoprodol and Xanax, even though he had not been on medications for five months and had tested negative for opiates, Mr. Parrado explained that "[t]here were some notations in his chart that caused me concern." *Id.* at 601. Mr. Parrado specifically noted the notation that SD "had not taken his medication in five months" and that his drug screen was negative for opiates "but yet he was prescribed a lethal dose of oxycodone that day." *Id.*

Asked on cross-examination that "you know that there's no ceiling on narcotics, don't you," Mr. Parrado answered: "[W]ell, but there is. On an opioid naïve patient there is." *Id.* at 601–02. Asked "[d]o you know whether S.D. was opioid naïve," Mr. Parrado testified: "[F]rom seeing the record, yes. He had not taken the medication in five months per his own dosing." *Id.* at 602. Mr. Parrado then added that the S.D.'s visit note stated that he had tested negative for opioids. *Id.* Asked if he knew from Respondent's Exhibit that "S.D. had been taking opioids for years?[26]", Mr. Parrado answered: "[y]es, but he had not taken them in five months per his own." *Id.* at 603. While Mr. Parrado acknowledged that he had no personal knowledge that S.D. had not taken the drugs for five months, Mr. Parrado explained: "[W]hat I'm talking about, if I as a pharmacist was looking at that chart and seeing that, I could not have dispensed that. My professional judgment would have prevented me from dispensing that prescription." *Id.* And after Respondent's counsel asked whether he knew if the notation meant "that the patient didn't get medication from the clinic for five months or whether . . . the patient was not seen at all anywhere for five months?", *id.* at 604, Mr. Parrado testified:

> The notations said, and if I'm going to be looking at a chart as a pharmacist to determine if there was something, if this dose is appropriate to begin with, the fact the patient said he had not taken the medication, I'm seeing in the medical record that the drug screen says opiate negative. That's telling me I now have an opioid naïve patient. I have a concern.

Id. at 605.

On further questioning by Respondent's counsel, Mr. Parrado reiterated that the patient's statement that he had not taken medication in five months "was in that chart that I looked at." *Id.* However, notwithstanding that Respondent obtained the visit note, which lists multiple controlled substance prescriptions that were issued to S.D. at his June 13, 2012 visit, the Government did not submit any prescriptions (and their labels) showing that Respondent actually dispensed any of the prescriptions listed in the visit note.

Discussion

Under the CSA, "[a] registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render [its] registration under section 823 of this title inconsistent with the public interest as determined under such section." 21 U.S.C. 824(a)(4). In the case of a retail pharmacy, which is deemed to be a practitioner, *see id.* § 802(21), Congress directed the Attorney General to consider the following factors in making the public interest determination:

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
>
> (2) The applicant's experience in dispensing or conducting research with respect to controlled substances.
>
> (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
>
> (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
>
> (5) Such other conduct which may threaten the public health and safety.

Id.

"[T]hese factors are . . . considered in the disjunctive." *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). It is well settled that I "may rely on any one or a combination of factors, and may give each factor the weight [I] deem[] appropriate in determining whether" to suspend or revoke an existing registration. *Id.; see also MacKay* v. *DEA,* 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *DEA,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I "need not make explicit findings as to each one." *MacKay,* 664 F.3d at 816 (quoting *Volkman,* 567 F.3d at 222); *see also Hoxie,* 419 F.3d at 482.[27]

Under the Agency's regulation, "[a]t any hearing for the revocation or suspension of a registration, the Administration shall have the burden of proving that the requirements for such revocation or suspension pursuant to . . . 21 U.S.C. [§]824(a) . . . are satisfied." 21 CFR 1301.44(e). In this matter, while I have considered all of the factors, the Government's evidence in support of its *prima facie* case is confined to factors two and four.[28] I find

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how I calculate it, it's not possible. And it is very hard to remember that. And I am a human being doing other business too, so I cannot remember everything, keep everything." *Id.* at 586–87.

While that may be, Respondent certainly knew what prescriptions were at issue well in advance of the hearing, and if it was true that Respondent was maintaining the due diligence checklists, Mr. George could have reviewed those checklists with respect to the patients who filled the prescriptions.

[26] Notwithstanding the question, there is nothing in the 16 pages of S.D.'s records that establish that he had been taking opioids for years. To be sure, there is a 2009 MRI report; a document indicating that a driver license check was performed on June 24, 2010, and another document indicating that S.D. made visits on monthly basis from August 12, 2011 through January 19, 2012, before reappearing five months later on June 13, 2012. However, the only evidence as to the prescriptions he had received prior to the June 2012 visit is the January 19, 2012 Progress Note and the prescription of the same date. In any event, Mr. Badawi was "still present in the hearing room" when Mr. Parrado was called in rebuttal and the ALJ explained that "if there's some expert conflict over this testimony, there's an opportunity for counsel to explore that." Tr. 597. Respondent did not call Mr. Badawi to challenge Mr. Parrado's testimony that S.D. was opioid naïve at the time he presented the June 2012 prescription.

[27] In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's or applicant's misconduct. *Jayam Krishna-Iyer,* 74 FR 459,462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821. Likewise, findings under a single factor can support the denial of an application.

[28] As to factor one, there is no evidence that the Florida Department of Health has either made a recommendation to the Agency with respect to Respondent, or taken any disciplinary action against Respondent. *See* 21 U.S.C. 823(f)(1). However, even assuming that Respondent currently possesses authority to dispense controlled substances under Florida law and thus meets a prerequisite for maintaining its registration, this finding is not dispositive of the public interest inquiry. *See Mortimer Levin,* 57 FR 8680, 8681 (1992) ("[T]he Controlled Substances Act requires that the Administrator . . . make an independent determination [from that made by state officials] as to whether the granting of controlled substance privileges would be in the public interest."). Accordingly, this factor is not dispositive either for, or against, the revocation of Respondent's registration. *Paul Weir Battershell,* 76 FR 44359, 44366 (2011) (citing *Edmund Chein,* 72 FR 6580, 6590 (2007), *pet. for rev. denied, Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008)).

As to factor three, I acknowledge that there is no evidence that Respondent, its owner, its manager, or any of its pharmacists, has been convicted of an that the record taken as a whole provides substantial evidence that Respondent's pharmacists violated their corresponding responsibility when they dispensed many of the prescriptions at issue. I also find that the Government has established by substantial evidence that Respondent has failed to maintain accurate records, as well as other violations. Accordingly, I conclude that the Government has established that Respondent has committed numerous acts which render its continued "registration inconsistent with the public interest." 21 U.S.C. 824(a)(4). Because I further agree with the ALJ's finding that Respondent has not accepted responsibility for its misconduct, I also agree with the ALJ that it has not rebutted the Government's *prima facie* showing. Because I find that Respondent's misconduct is egregious, I will order that Respondent's registration be revoked and that any pending application be denied.

Factors Two and Four—The Respondent's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

The Dispensing Allegations

"Except as authorized by" the CSA, it is "unlawful for any person [to] knowingly or intentionally . . . manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance." 21 U.S.C. 841(a)(1). Under the Act, a pharmacy's registration authorizes it "to dispense," *id.* § 823(f), which "means to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner." *Id.* § 802(10).

The CSA's implementing regulations set forth the standard for a lawful controlled substance prescription. 21 CFR 1306.04(a). Under the regulation, "[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." *Id.* Continuing, the regulation provides that:

> [T]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, *but a corresponding responsibility rests with the pharmacist who fills the prescription.* An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person *knowingly filling* such a purported prescription . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.[29]

Id. (emphasis added).

As the Agency has made clear, to prove a violation of the corresponding responsibility, the Government must show that the pharmacist acted with the requisite degree of scienter. *See JM Pharmacy Group, Inc., d/b/a Farmacia Nueva and Best Pharma Corp.,* 80 FR 28667, 28669 (2015). Thus, the Government can prove a violation by showing either that: (1) The pharmacist filled a prescription notwithstanding his/her actual knowledge that the prescription lacked a legitimate medical purpose; or (2) the pharmacist was willfully blind (or deliberately ignorant) to the fact that the prescription lacked a legitimate medical purpose. *See id.* at 28671–72. As to establishing that a pharmacist acted with "willful blindness, proof is required that: '(1) The defendant must subjectively believe that there is a high probability that a fact exists and (2) the defendant must take deliberate actions to avoid learning of that fact.'" *Id.* at 28672 (quoting *Global-Tech Appliances, Inc.,* v. *SEB S.A.,* 563 U.S. 754, 769 (2011)).

Here, the Government makes no claim that any of Respondents' pharmacists dispensed the prescriptions having actual knowledge that the prescriptions lacked a legitimate medical purpose. Instead, relying primarily on *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195,* 77 FR 62316, 62341 (2012), the Government argues that a pharmacist violates the corresponding responsibility rule when he/she dispenses a controlled substance prescription "in the face of a red flag (*i.e.*[,] a circumstance that does or should raise a reasonable suspicion as to the validity of a prescription) unless he . . . takes steps to resolve the red flag and ensure that the prescription is valid." Gov. Post-Hrng. Br. 21.

The Government argues that Respondent's pharmacists violated this regulation by filling prescriptions for such drugs such oxycodone, hydromorphone, and MS Contin (morphine sulfate) which presented various "red flags" which were never resolved. Gov. Post-Hrng. Br. 22–24. It contends that its expert, Mr. Parrado, gave "unrefuted testimony" that "Respondent repeatedly distributed controlled substances pursuant to prescriptions that contained one or more unresolved red flags for diversion." *Id.* at 22. And after listing six different circumstances which Mr. Parrado identified as presenting red flags, it argues that he "testified that no evidence could be found to show the red flags had been resolved prior to dispensing." *Id.* As evidence that the red flags were not resolved, it relies on Mr. Parrado's testimony that it is the standard of pharmacy practice that the resolution of a red flag is documented on the prescription itself and that none of the prescriptions entered into evidence contain any such documentation.[30] *Id.* at 23.

However, with the exception of a provision of Florida law which requires that a pharmacist document that he has checked a patient's identification (or made a photocopy of the identification and attached it to the prescription), no provision of the CSA, DEA regulations, Florida law, or the Board of Pharmacy's rules requires that a pharmacist document the resolution of a red flag or flags on the prescription itself. While it may be the custom of the pharmacy profession to document the resolution of a red flag or flags on the prescription, that does not make it improper to document the resolution someplace else.

Recently, I rejected allegations that a registrant's pharmacists had failed to resolve red flags when the only evidence the Government offered to prove that fact was the absence of

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offense under either federal or Florida law "relating to the manufacture, distribution or dispensing of controlled substances." 21 U.S.C. 823(f)(3). However, there are a number of reasons why even a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay,* 75 FR 49956, 49973 (2010), *pet. for rev. denied, MacKay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011). The Agency has therefore held that "the absence of such a conviction is of considerably less consequence in the public interest inquiry" and is therefore not dispositive. *Id.*

While the Government did not allege in the Show Cause Order any misconduct with respect to factor five, following the hearing, the Government argued that Mr. George provided incredible testimony. Because I consider his testimony in evaluating the evidence as to the dispensing allegations, as well as whether Respondent has credibly accepted responsibility for its misconduct, I deem it unnecessary to separately address Mr. George's testimony under factor five.

[29] As the Supreme Court has explained, "the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, the provision also bars doctors from peddling to patients who crave the drugs for those prohibited uses." *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006) (citing *United States* v. *Moore,* 423 U.S. 122, 135, 143 (1975)).

[30] In fact, the record includes several prescriptions which contain notations on the back of the prescriptions suggesting a phone call was made to someone about the prescriptions. GX 14, at 7–10. These prescriptions were issued by a doctor at a clinic other than 24th Century. *See id.* at 7, 9. However, the Government did not ask Mr. George to explain the notations even though his initials are on the dispensing labels as the dispensing pharmacist.

documentation on the prescriptions themselves. *See Superior Pharmacy I and II,* 81 FR 31310 (2016). In *Superior,* I noted that "while evidence of a custom certainly has probative value, it is not conclusive proof." *Id.* at 31335 n. 55 (citing *Sorrels* v. *NCL (Bahamas) Ltd.,* 796 F.3d 1275, 1282 (11th Cir. 2015) ("[E]vidence of custom within a particular industry, group, or organization is admissible as bearing on the standard of care in determining negligence. Compliance or noncompliance with such custom, though *not conclusive* on the issue of negligence is one of the factors the trier of fact may consider in applying the standard of care.") (emphasis added) (quoting *Muncie Aviation Corp.* v. *Party Doll Fleet, Inc.,* 519 F.2d 1178, 1180–81 (5th Cir. 1975))). *See also* II Wigmore, Evidence, § 379, at 403 (Tillers rev. ed. 1983) (explaining that with respect to evidence of custom or usage of trade, "the question is not whether the offered instances fully prove the custom alleged, but merely whether they are receivable as having probative value"). Thus, while the absence of documentation on the prescriptions is clearly probative evidence that Respondent's pharmacists failed to resolve the strong suspicion presented by many of the prescriptions—indeed, Mr. George testified that he previously documented the resolution of red flags on the prescriptions until 2010 when he started using the due diligence checklists, Tr. 455–57,—the absence of documentation on the prescriptions is not conclusive proof that Respondent's pharmacists failed to do so.

Moreover, while there is no requirement that a pharmacist document the resolution of a red flag on a prescription, a regulation of the Florida Board of Pharmacy (then in effect) specifically required that "[a] patient record system . . . be maintained by all pharmacies for patients to whom new or refill prescriptions are dispensed" and that the "system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a new or refill prescription is presented for dispensing." Fla. Admin. Code r. 64B–16–27.800. This rule also required that the pharmacy maintain "[a] list of all new and refill prescriptions obtained by the patient at the pharmacy . . . during the two years immediately preceding the most recent entry" and include the "prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber.[31]" *Id.*

The rule further required that the record include the "[p]harmacist['s] comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug." *Id.* And the rule also required that the pharmacist make "a reasonable effort . . . to obtain from the patient . . . and record any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs . . . being used by the patient which may relate to prospective drug review." *Id.* Finally, the rule required that "[t]he pharmacist . . . record any related information indicated by a licensed health care practitioner." *Id.*

Of further note, the Board of Pharmacy's rules require that a pharmacist "review the patient record and each new and refill prescription presented for dispensing in order to promote therapeutic appropriateness." Fla Admin Code r. 64B16–27.810. This rule specifically requires that a pharmacist identify such issues as: "[o]ver-utilization," "[t]herapeutic duplication," "[d]rug-drug interactions," "[i]ncorrect drug dosage," and "[c]linical abuse/misuse." *Id.*

Notwithstanding that the Board's rule specifically requires that a pharmacist document in the patient record his/her comments relevant to the patient's drug therapy and "other information peculiar to the patient" or drug, as well as "any related information" provided by the patient's physician, and thus, would seem to provide relevant evidence in assessing whether a pharmacist resolved the suspicion created by the prescriptions, the Government did not introduce any of the patient profiles. Nor did it provide any of the patient profiles to Mr. Parrado, Tr. 300, even though on cross-examination, he acknowledged that a pharmacist would generally need to see the patient profile to determine whether a patient had developed tolerance.[32] *Id.* at 151.

In *Superior Pharmacy I and II,* I found the Government's evidence, which was limited to the prescriptions (which contained no documentation that the red flags were resolved) and its Expert's testimony, insufficient to establish that the pharmacists violated their corresponding responsibility. Here, however, there is additional evidence, which establishes by a preponderance of the evidence, that Respondent's pharmacists acted knowingly or with willful blindness when they dispensed at least some of the prescriptions, which lacked a legitimate medical purpose. More specifically, both Mr. George's testimony and the partial medical records support this finding with respect to some of the prescriptions.

At the outset, the evidence shows that more than 90 percent of the schedule II prescriptions Respondent filled between January 3, 2011 and February 4, 2013 were written by doctors employed by Victor Obi, the brother of Respondent's owner. GX 12, at 2. *See also, e.g., United States* v. *Leal,* 75 F.3d 219, 223 (6th Cir. 1996) (holding that where "more than 90% of the prescriptions" a pharmacist filled were written by one doctor was probative evidence that pharmacist knew of illegitimate prescribing practice). Mr. George clearly knew that the overwhelming majority of the schedule II prescriptions Respondent filled were issued by Mr. Obi's employees.

As found above, on July 28, 2011, Respondent dispensed 210 tablets of oxycodone 30 to T.V., who had travelled 472 miles from Pensacola to obtain a prescription from Dr. P.C., one of the doctors at 24th Century. GX 3, at 1. I find that the distance T.V. travelled to obtain the prescription, as well as the drug—a known drug of abuse—and dosing, were sufficient to establish a subjective belief on the part of the pharmacist who filled the prescription that there was a high probability that the prescription lacked a legitimate medical purpose.[33] Indeed, Mr. George

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[31] This rule remains in effect today; however, the rule now requires that the information be maintained for a period of four years preceding the most recent entry.

[32] It is not that the patient profiles were unobtainable, as the evidence shows that Respondent's computer was digitally imaged by the AIW team, Tr. 217, 301; and thus, the profiles could have been extracted.

[33] Respondent argues that the Government cannot establish that a pharmacist has violated his corresponding responsibility unless it first establishes that the prescription lacked a legitimate medical purpose and that the issuing physician acted outside of the usual course of professional practice. Resp.'s Exceptions, at 9. It argues that "neither the fact of this corresponding responsibility nor the pharmacist's performance of his corresponding responsibility affects whether the prescription was, in the first place, issued to the patient for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." *Id.* And it further argues that "the test for the proper dispensing of a controlled substances remains at its foundation a medical question" and that "the Government provided not one scintilla of evidence to prove that the prescriptions at issue were issued for other than a legitimate medical purpose." *Id.* at 9–10.

Respondent is mistaken. While it is true that a pharmacist cannot violate his corresponding responsibility if a prescription was nonetheless issued for a legitimate medical purpose, Respondent ignores that the invalidity of a prescription can be proved by circumstantial evidence. *See, e.g., United States* v. *Leal,* 75 F.3d acknowledged that the distance T.V. was travelling was a red flag. Tr. 494.

Regarding T.V., Mr. George testified that she had been a patient since 2009, that she had shown him scars from back surgeries, and that "even though the distance was far," his experience and "the need of the patients" [sic] led him to fill the prescription. *Id.* at 494–95. Mr. George further justified dispensing T.V.'s prescriptions,[34] explaining that she had multiple surgeries at Tampa General Hospital when Dr. Ruperto was its Chief Anesthesiologist, and that he had become the director of the 24th Century clinic. *Id.* at 588. Mr. George then explained T.V. "used to come *and see that doctor always.* And while I was interviewing that patient she said she likes the doctor and she wanted to continue seeing that doctor. That's why she was coming from that 450 miles." *Id.* (emphasis added).

Dr. Ruperto did not, however, issue the July 28, 2011 prescription. Indeed, his name does not appear among the lists of physicians on any of the 24th Century prescriptions. And while Mr. George testified that T.V. saw Dr. Ruperto "always" because she liked the doctor and that she had been coming to Respondent "from 2009 onwards," Dr. Ruperto had died in December 2008, before T.V. had even started patronizing Respondent. I thus find that Mr. George's testimony as to why Respondent filled the prescription disingenuous. And I further conclude that Respondent's pharmacist knowingly filled an unlawful prescription.

On January 19, 2012, Respondent dispensed 120 tablets of oxycodone 30 to S.D., who had travelled 331 miles from Panama City to obtain the prescription from Dr. R.R. of the 24th Century Clinic. GX 3, at 33. In addition to the strong suspicion created by the distance S.D. had travelled, the partial medical records—which Mr. George testified he would obtain and review before dispensing—show that Dr. R.R. prescribed five different controlled substances to S.D. at this visit including oxycodone, MS Contin, Soma (carisoprodol), Xanax and Dilaudid, the latter being added at this visit. RX 3, at 29; *see also id.* at 27.

Thus, S.D.'s partial medical record created additional strong grounds for Mr. George (whose initials are on the prescription label as the dispensing pharmacist) to subjectively believe that there was a high probability that the prescriptions lacked a legitimate medical purpose. First, the record showed that Dr. R.R. had prescribed a drug cocktail of CNS depressants of opiates (oxycodone), benzodiazepines, and carisoprodol, which as Mr. Parrado explained, is known as the Holy Trinity and to be highly abused on the street. Notably, Mr. Badawi offered no testimony refuting Mr. Parrado on this issue. And while Mr. George denied being familiar with drug cocktails, Tr. 563–64, DEA had identified this combination of drugs in several final decisions as being highly abused prior to the events at issue here. *See Paul Volkman,* 73 FR 30630, 30637 (2008); *see also East Main Street Pharmacy,* 75 FR 66149, 66157–58 (2010).

Mr. Parrado also testified that the maximum recommended dose of Dilaudid (hydromorphone) was 24 mg per day and that patients usually do not take the eight milligram dosage unless they have terminal cancer; he also testified that prescribing two short acting opiates is inappropriate therapy and raises a red flag. *Id.* at 57–58. As to Mr. Parrado's testimony regarding the maximum recommended dosing of Dilaudid, Mr. Badawi offered no testimony in refutation and he also agreed that prescribing a quantity "larger than the manufacturer's recommended dosage" creates a red flag. *Id.* at 402–03. Nor did Mr. Badawi offer any testimony refuting Mr. Parrado's testimony that the eight milligram dose was not usually prescribed unless the patient had terminal cancer. *See generally id.* at 402–40. Of note, neither of the progress notes in S.D.'s partial medical file indicates that he had been diagnosed with cancer of any stage, let alone terminal. RX 3, at 28–29 (Jan. 19, 2012 visit); *id.* at 26 (June 13, 2012).

Mr. Badawi also agreed with Mr. Parrado that the prescribing of two short-acting opiates together is a red flag that would require further investigation. Tr. 419. He then testified that a patient with kidney failure who undergoes dialysis could legitimately require two short-acting opiates. There is, however, no documentation on either progress note that S.D. had kidney failure. RX 3, at 25–29. And while Mr. Parrado acknowledged that prescribing an extended release drug would be problematic for a patient who had undergone bariatric surgery, S.D. was prescribed MS Contin, which is an extended-release drug.[35]

Of further note, Mr. George testified that he had reviewed S.D.'s partial file before dispensing the prescription. Tr. 560–61. However, Mr. George offered no testimony other than his generalized assertion that he always did his due diligence, which neither the ALJ nor I find credible, to explain how he resolved the suspicion created by S.D.'s prescriptions. Thus, given the sum total

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219, 223 (6th Cir. 1996); *United States* v. *Veal,* 23 F.3d 985, 988 (6th Cir. 1994) (per curiam); *United States* v. *Hayes,* 595 F.2d 258, 261 (5th Cir. 1979). I find that to be the case here. For similar reason, I reject Respondent's contention that the Government failed to meet its burden because Mr. Parrado is a pharmacist with "no medical training or experience that would have allowed him to evaluate the legitimacy of a physician's prescribing." Resp. Exceptions, at 20.

In its Exceptions, Respondent also argues that "[i]n *Holiday CVS,* there was evidence that two prescribers lacked a valid DEA registration" and that "[t]here was also evidence that the red flags were irresolvable." Exceptions, at 10. Respondent then argues that the decision's "three-factor test is therefore founded upon evidence that prescriptions were, in fact, issued outside the usual course of professional practice (*e.g.,* by a prescriber without a valid DEA registration)[,]" and that [h]aving established the threshold question, the three-factor test was applied to determine if all of the red flags that a reasonably prudent pharmacist would have identified were conclusively resolved prior to dispensing." *Id.*

Here too, Respondent is mistaken. To be sure, in *Holiday CVS,* the Agency relied in part on the prescriptions the two pharmacies filled that had been written by two physicians who were no longer registered (one had allowed his registration to expire, the other's registration had been revoked). 77 FR at 62316. With respect to these prescriptions, the Agency did so because the evidence showed that the pharmacies subscribed to a database which compiles information as to physicians' registration status, and thus, the pharmacists should have known that the physicians were no longer registered; the order also noted that in the case of the doctor whose registration had been revoked, that order was published in the **Federal Register** and yet one the pharmacies was still filling his prescriptions more than six months later. *Id.* These prescriptions were not merely suspicious, they were flat out illegal, and as such, there was nothing for the pharmacists to resolve, as under no circumstance could they be lawfully filled. *See* 21 CFR 1306.03(a).

This, however, was only one part—and a small part—of the case, and the three-part test was discussed in the context of the pharmacies' decisions to dispense prescriptions for oxycodone 30 and alprazolam 2, which were written by doctors in South Florida for patients, many of whom had travelled from out-of-state (*e.g.,* Kentucky and Tennessee) to the pharmacies which were located in Sanford, Florida, 200 miles or more from the physicians. *Id.* at 62318. Of further note, in *Holiday CVS,* while the Government sponsored the testimony of an expert in pharmacy practice, it did not offer any testimony from a physician as to the medical propriety of the prescriptions. *See generally id.* at 62325–34 (recommended decision's discussion of Government' evidence). Here too, the Government relied on the circumstantial evidence that the prescriptions lacked a legitimate medical purpose. Accordingly, I reject Respondent's contention that "the Government provided not one scintilla of evidence to prove that the prescriptions . . . were issued for other than a legitimate medical purpose." Resp. Exceptions, at 10.

[34] While there is only one prescription for T.V. in the record, Mr. George's testimony suggests that there were other prescriptions that Respondent had filled for her.

[35] While Mr. George asserted that a patient could have allergies and thus need to be prescribed two short-acting medications, here too, there is no evidence in either progress note that S.D. had such an allergy.

of the information Mr. George had available to him when he dispensed oxycodone to S.D., I find that Mr. George was willfully blind to the fact that the prescription he dispensed lacked a legitimate medical purpose.

Likewise, the partial medical record for H.C., Jr., shows that on December 6, 2012, he, too, received the cocktail known as the Holy Trinity from Dr. R.R. of the 24th Century Clinic. RX 3, at 47. More specifically, he received a prescription for 180 oxycodone 30 mg, along with prescriptions for 112 tablets of OxyContin 40 mg, 84 tablets of carisoprodol 350 mg, and 84 tablets of Xanax (alprazolam) 1 mg. *Id.* The evidence further showed that he paid $1350 just to fill the oxycodone 30 prescription. GX 3, at 35.

Mr. George offered a lengthy explanation as to why he had filled H.C., Jr.'s, prescription. More specifically, Mr. George explained that H.C., Jr., had been a patient who previously had insurance, that for two years he did not come to the pharmacy, and that when he returned he had lost his insurance but said he needed the medication and brought Mr. George a profile showing he had been on the medication and was "willing to pay whatever the cash price at that time." Tr. 496–97. While Mr. George asserted that when he got the oxycodone 30 prescription, he did his due diligence and followed his protocols and determined that H.C., Jr. had a bulging disc, *id.*at 496, he offered no testimony specifically explaining what steps he took to resolve the high degree of suspicion which arose from H.C., Jr.'s being prescribed this highly abused combination of drugs by Dr. R.R. or any other physician who had previously prescribed this combination of drugs to H.C., Jr. I thus find that Mr. George subjectively believed that there was a high probability that the prescription lacked a legitimate medical purpose and that he deliberately avoided learning of this fact. And Mr. George offered no testimony as to why he also filled an oxycodone 30 prescription of the same quantity for H.C., Sr.

The evidence also shows that on the same day, J.P. and T.P. who, according to Mr. George, were husband and wife, travelled 196 miles from St. Augustine to 24th Century, where they obtained prescriptions for 196 and 224 tablets respectively of oxycodone 30. GX 3, at 2–3. The sequential prescription numbers also support the inference that J.P. and T.P. presented their prescriptions to Mr. George one after the other, which he then filled.[36] GX 3, at 2–3.

Mr. George asserted that he remembered the case of J.P. and T.P. "in detail." Tr. 468. He asserted that T.P. had a bulged disc from an accident in 1998 and "was our patient from 2009" and that J.P. had a "motor vehicle accident" and "had problems with his neck and . . . back"; however, he offered no evidence as to when J.P.'s accident had occurred and how long he had been a patient. *Id.*

Here, notwithstanding Mr. George's statement that he remembered the case "in detail," he offered no testimony as to why T.P. and J.P. needed to travel 196 miles each way to obtain medication for their purported conditions when there were likely a number of other clinics where they could have obtained treatment that are located far closer to St. Augustine then the 24th Century clinic. And while Mr. George asserted that he filled the prescriptions because he "was comfortable within [his] professional judgment" "after doing all the due diligence and following the protocols, talking to the doctors," *id.*at 573, Respondent produced no evidence to corroborate his testimony, not even the two-page due diligence checklists for T.P. and J.P.

Notably, the ALJ did not find Mr. George's testimony credible,[37] nor do I. Indeed, I conclude that the exact opposite of what Mr. George testified to is true. *See, e.g., NLRB* v. *Walton Manufacturing Co.,* 369 U.S. 404, 408 (1962) (quoting *Dyer* v. *McDougall,* 201 F.2d 265, 269 (2d Cir. 1952) ("the demeanor of a witness . . . 'may satisfy the tribunal, not only that the witness' testimony is not true, but that the truth is the opposite of his story; for the denial of one who has a motive to deny, may be uttered with such hesitation, discomfort, arrogance or defiance, as to give assurance that he is fabricating, and that, if he is, there is no alternative but to assume the truth of what he denies' ")).[38] I therefore conclude that Mr. George either knew that the prescriptions T.P. and J.P. presented lacked a legitimate medical purpose or subjectively believed that there was a high probability that the oxycodone prescriptions he filled for T.P. and J.P. on August 4, 2011 lacked a legitimate medical purpose and that Mr. George deliberately avoided learning of this fact.

On April 21, 2011, Mr. George dispensed a prescription for 196 oxycodone 30 to C.B., which was written by Dr. P.C. of the 24th Century clinic. Tr. 569; GX 3, at 16. C.B. lived in Big Pine Key, which is near Key West and a distance of 400 miles from Respondent. GX 3, at 16; R.D. at 6.

Asked if he knew where Big Pine Key is, Mr. George answered that he knew it was in Florida. Asked if he recalled investigating why C.B. had travelled from Big Pine Key to Tampa to get the prescription, Mr. George asserted that he didn't "remember particularly this patient again." Tr. 569. He then offered a generalized explanation as to why patients had addresses indicating that they lived a considerable distance from Tampa, such as "their [sic] spouse are [sic] living in Tampa, they're [sic] in job assignment, or their [sic] doctor is here and they like the doctor," before acknowledging that "I don't particularly remember" the patient. *Id.* Here again, he asserted that "definitely I did counsel the patient and record it in the due diligence sheet why they travel." *Id.* at 573. However, Respondent failed to produce the due diligence sheets to corroborate Mr. George's testimony.

Here again, I conclude that the exact opposite of what Mr. George testified to is true—that he did not determine why C.B. had travelled from Big Pine Key to fill the prescription. *Walton Manufacturing Co.,* 369 U.S. at 408 (quoting *Dyer* v. *McDougall,* 201 F.2d at 269). And I further conclude that Mr. George either knew that the prescription lacked a legitimate medical purpose or subjectively believed that there was a high probability that the prescription C.B. presented lacked a legitimate medical purpose and that he deliberately avoided learning of that fact.

Mr. George did not otherwise address how he resolved the various red flags presented by any other specific prescription. As for the remaining prescriptions, he testified that he had used the protocol he described in dispensing the prescriptions, Tr. 451, that he resolved all of the red flags, and that he documented his resolution of all of the red flags on the due diligence checklists which were in the binder in the pharmacy. *Id.* at 552–53. The ALJ specifically found that Mr. George did not "credibly assert[ ] that he took this action for each of the prescriptions entered into this record." R.D. 48. And she further found that he did not provide any other "evidence that he utilized this system in regards to the 85 prescriptions in this record that contain red flags." *Id.*

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[36] Both prescription labels include the initials "KG." GX 3, at 2–3.

[37] There are numerous examples that support the ALJ's finding that Mr. George's testimony was incredible. One such example is his story of how, in 2012, he discovered that J.P. had been discharged from 24th Century clinic after the clinic determined that J.P. had tested positive for cocaine during an admission to a hospital in St. Augustine. According to Mr. George, this occurred when J.P. attempted to fill a prescription. Mr. George did not explain why J.P. would even have a prescription if he had been discharged by the clinic.

[38] I thus reject Respondent's contention (Resp. Exceptions, at 11–13) that the ALJ improperly drew the adverse inference that Mr. George's testimony was not credible when he testified that he "always" conducted his due diligence. Respondent also argues that the ALJ's credibility finding is not supported by substantial evidence because "the record lacks any evidence that Mr. George *failed* to utilize a system for resolving the red flags presented by the prescriptions at issue" and that his testimony was unrefuted. *See also id.* at 38–39. Contrary to Respondent's understanding, the ALJ, who observed Mr. George testify, could reasonably find that "the opposite of his story" is true based solely on her observation of him. *Walton Manufacturing,* 369 U.S. at 408 (quoting *Dyer,* 201 F.2d at 269).

Relying on *International Union (UAW)* v. *NLRB,* 459 F.2d 1329, 1336 (D.C. Cir. 1972), the ALJ concluded that "an adverse inference" was warranted as "[e]ither the due diligence files do not exist, or the files present evidence that is adverse to the Respondent's case." R.D. 49. The ALJ thus concluded that "[t]he Government has . . . proved that the Respondent filled prescriptions that presented red flags, and the red flags were not otherwise resolved prior to the pharmacy dispensing such prescriptions. Respondent's inaction in failing to resolve these red flags violates the pharmacy's corresponding responsibility." *Id.* (citing 21 CFR 1306.04(a); *Holiday CVS, LLC, d/b/a CVS Pharmacy Nos. 219 and 5195,* 77 FR 62316 (2012)).

I agree with the ALJ that an adverse inference is warranted based on Respondent's failure to produce the due diligence checklists and her assessment of Mr. George's credibility on the issue of whether he resolved all of the red flags. I nonetheless do not adopt her conclusion that Respondent's pharmacists violated their corresponding responsibility with respect to *each* of the 85 prescriptions in the record.

In *Superior,* I noted that *Holiday CVS* defines the term "red flag" to mean "a circumstance that does or should raise a reasonable suspicion as to the validity of a prescription." 81 FR at 31335. I further explained that "[a]ll red flags do not have the same hue" and that "proof that a pharmacist dispensed a controlled substance prescription without resolving a red flag which only created a 'reasonable suspicion' that the prescription lacked a legitimate medical purpose, is not enough to establish that a pharmacist acted with the requisite scienter" of willful blindness, and thus violated 21 CFR 1306.04(a). *Id.* at n.54; *see also Global-Tech,* 563 U.S. at 769. However, I also noted that even "where there are multiple red flags, none of which alone would establish the requisite scienter, the combination of red flags may well create a subjective belief that there is a high probability that a prescription lacks a legitimate medical purpose." 81 FR at 31335 n.54.

As explained above, establishing the requisite scienter for a violation requires more than simply showing that a prescription presented a red flag. The ALJ, however, simply concluded that because each of the prescriptions presented a red flag or flags, without any assessment of the level of suspicion created by the red flag or flags, a violation was established because she found Mr. George not credible when he testified that he resolved all of the red flags. This approach is too untethered to the text of 21 CFR 1306.04(a) to support findings that Respondent's pharmacists either acted knowingly or with willful blindness when they dispensed each of the prescriptions.

To demonstrate, the record contains multiple prescriptions for MS Contin. The record is, however, devoid of any evidence as to why the quantities prescribed were suspicious, and certainly the prices paid for the prescriptions are not so outlandish as to support the conclusion that only a person who was abusing the drugs or selling them to others would be willing pay the amount charged by Respondent for the drug.[39] Nor, despite its placement in Schedule II of the CSA, is there any evidence that MS Contin was known to be highly sought after by drug abusers. Thus, the only red flag presented are the distances travelled by the patients. Even then, however, a number of the persons filling the prescriptions lived in towns, such as Tarpon Springs and Spring Hill, which are within commuting range of Tampa. As to these prescriptions, it is unclear why the distance travelled by the patient was enough to establish that the pharmacist (whether Mr. George or others) subjectively believed that there was a high probability that the prescription lacked a legitimate medical purpose.[40] This is so even when coupled with Mr. George's knowledge that 90 percent of the prescriptions were being issued by Mr. Obi's employees.

The record does, however, establish that Respondent filled multiple prescriptions for Dilaudid (hydromorphone) which authorized the dispensing of high quantities and called for daily dosing well above the 12–24 milligrams average daily dose. Specifically, Mr. George dispensed 240 tablets of Dilaudid 8 mg to D.K., which would provide a daily dose of 64 mg, and 196 tablets of Dilaudid 8 mg to G.C., which would provide a daily dose of approximately 52 mg.

As noted previously, Mr. Parrado provided unrefuted testimony that Dilaudid 8 mg is an "extremely, extremely potent opioid," that the dose was "almost double the recommended upper daily dose" (it was actually more), and that the prescription provided "a high dose because mostly people don't take Dilaudid 8 [mg] unless they're in a terminal stage of cancer." Tr. 90. Mr. Parrado then testified that "[t]o see multiple prescriptions for 200 tablets would be almost a non-resolvable red flag to me." *Id.* I conclude that Mr. Parrado's unrefuted testimony on this issue provides substantial evidence that Mr. George subjectively believed that there was a high probability that these prescriptions were not issued for a legitimate medical purpose.

As for whether Mr. George resolved the high probability that the prescriptions were illegitimate raised by their dosing and quantity, Mr. George did not specifically address these two prescriptions. To be sure, Mr. George testified as a general matter that he resolved the suspicion presented when a prescription authorizes the dispensing of a controlled substance in quantities and dosing which exceed the maximum recommended dose in opioid naïve patients by looking at the patient profiles to see if the patient had developed tolerance. However, while looking at a patient profile to determine how large a quantity a patient had previously been prescribed might well resolve whether a patient has developed tolerance, it does not conclusively resolve the issue of whether a prescription was issued for a legitimate medical purpose. *See T.J. McNichol,* 77 FR 57133, 57148 (2012). Indeed, just as legitimate patients may, over time, require larger prescriptions to obtain the same level of analgesia, so too, addicted persons require larger doses to obtain the same high. Also, a patient who seeks prescription narcotics for the purpose of reselling them has an economic incentive to seek large quantities.

Moreover, Mr. George testified that while he always documented how he resolved the suspicion presented by a prescription, and, consistent with Mr. Parrado's testimony as to the standard of practice, that he had formerly done so on the prescriptions themselves, Mr. George then maintained that from 2010 onwards he started doing so on the due diligence checklists. Yet, even though Respondent knew what prescriptions were at issue, it failed to produce the due diligence checklists for the patients who received these prescriptions. And while Respondent chose to put Mr. George on the stand, Mr. George did not address how he resolved the suspicious circumstances presented by these two prescriptions.[41]

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[39] The most expensive prescription was for 84 tablets of MS Contin 100 mg and cost $218.40. GX 14, at 23–24. Yet other prescriptions cost as little as $25.20. GX 13, at 5–6.

[40] It is acknowledged that some of the patients who filled the MS Contin prescriptions came from such places as Ocala, Gainesville and St. Augustine (196 miles). However, I deem it unnecessary to decide whether each of these prescriptions was unlawfully dispensed.

Thus, I find that Mr. George either knew that the Dilaudid prescriptions issued to D.K. and G.C. lacked a legitimate medical purpose or subjectively believed that there was a high probability that the prescriptions lacked a legitimate medical purpose. I further find that an adverse inference is warranted that Respondent did not conclusively resolve the high probability that the Dilaudid prescriptions issued to D.K. and G.C. lacked a legitimate medical purpose. I therefore conclude that substantial evidence supports a finding that Mr. George violated 21 CFR 1306.04(a) when he dispensed these two prescriptions.[42]

Mr. Parrado also identified as suspicious two instances in which patients (B.W. and T.F.) presented prescriptions for both Dilaudid 8 and methadone 10 which were issued on the same day. Tr. 107–11. Mr. George filled B.W.'s prescriptions, which were for 100 Dilaudid 8 mg and 60 methadone 10 mg, notwithstanding that: (1) B.W. had travelled from Tallevast (54 miles from Respondent); (2) the dosing instruction for the Dilaudid was to take one tablet every four hours for pain, thus resulting in a daily doses of 48 mg, double the upper recommended dose; and (3) that Dilaudid and methadone "are immediate release opioids, both of which could contribute to respiratory depression, which could be a serious concern,"; and (4) while methadone's analgesic effect peaks at "three to four hours and tapers off rather quickly," the respiratory depression effects continue to grow. Tr. 107, 174.

Notably, even Mr. Badawi agreed that the simultaneous prescribing of two immediate release narcotics presents a red flag which requires further investigation. *Id.* at 418–19. And while the record includes evidence that there may be instances in which it is appropriate to prescribe two short-acting narcotics due to kidney failure (and perhaps an allergy), Mr. George offered no explanation as to how he resolved the high probability that the prescriptions lacked a legitimate medical purpose and decided to dispense the prescriptions.[43]

In addition to the oxycodone 30 prescriptions Respondent dispensed to T.V., J.P., T.P., H.C., Jr., and C.B., the record contains an additional 29 oxycodone prescriptions which provided for the dispensing of quantities and dosing in excess of the 80 mg daily limit. Notably, 25 of the prescriptions provided for the dispensing of 168 du or more, and 13 of the prescriptions provided for the dispensing of 224 du or more. *See generally* GX 3; GX 13. Moreover, most of the prescriptions for 168 du provided a dosing instruction of one tablet every four hours, for a total of 180 mg per day, and the prescriptions for 224 du typically provided a dosing instruction of one tablet every three to four hours, for up to 240 mg per day. *See* GX 3, at 8–9, 12–13, 19, 23, 30; GX 13, at 39 (prescriptions for 168 du); *see also* GX 3, at 3, 4–5,10–11, 14–15, 17, 20, 24, 26, 28, 29; GX 13, at 1–2, 3–4, 37–38 (prescriptions for 224 du or more).[44]

As Mr. Parrado testified, "[o]ne of the things that a pharmacist knows or should know is that oxycodone . . . 80 milligrams a day has been listed in the literature as a lethal dose for or an opioid naïve patient. So, when being presented with a prescription for a dose that would exceed 80 milligrams in one day, that pharmacist would need to stop and take a look and verify that the patient[ ] is not opioid naïve and has been on a regimen[ ] that has led him to develop a tolerance to that dose." Tr. 57. Mr. Badawi did not refute Mr. Parrado's testimony as to the maximum recommended dose for an opioid naïve patient and he agreed that when a prescription calls for the dispensing of a "very large or larger than normal amounts of a narcotic," or an amount "larger than the manufacturer's recommended dosage," a pharmacist must make an inquiry. *Id.* at 402–03. While Mr. Badawi then testified that looking at the patient profile would show whether the patient has developed tolerance, as explained previously, even if the profile shows that the patient has previously received large doses, this does not conclusively resolve the issue of whether the prescription was issued for a legitimate medical purpose.

Here, the Government produced numerous prescriptions which provided quantities and dosing instructions that were two to three times the 80 milligram level. Moreover, Mr. George acknowledged that a prescription that exceeds the manufacturer's recommended daily dosage presents a red flag, and I conclude that when a narcotic prescription exceeds that dosage by the amounts present here, that red flag establishes that there was a high probability that the prescription lacks a legitimate medical purpose and that Mr. George subjectively believed as much.

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[41] While I rejected similar allegations in *Superior I and II* because the evidence that the pharmacists had failed to resolve the suspicious circumstances was limited to the absence of such documentation on the prescriptions and faulted the Government for failing to produce the patient profiles, in that matter, neither party called any of the pharmacists who dispensed the prescriptions.

I also note that after the Government rested, Respondent sought partial summary disposition on the dispensing allegations arguing that the Government did not "meet its burden of proof to show that the red flags were not resolved" and that all that "the Government has proven is that the resolution of the red flags was not present on the back of the prescriptions." Tr. 336. The ALJ denied the motion, ruling that "Respondent has not provided any legal authority that supports [its] position that I can grant summary disposition of an issue in the course of this hearing," and that she only had authority to recommend that I grant summary disposition. *Id.* at 340.

Even if the ALJ committed error when she denied Respondent's motion, Respondent had the option of not putting forward evidence on the dispensing allegations. Respondent nonetheless chose to present Mr. George's testimony and submit the partial medical records. *Cf. United States* v. *Sherod,* 960 F.2d 1075, 1076 (1992) ("It is the universal rule in the federal circuits that 'a criminal defendant who, after denial of a motion for judgment of acquittal at the close of the government's case-in-chief, proceeds to the presentation of his own case, waives his objection to the denial.' ") (quoting *United States* v. *Foster,* 783 F.2d 1082, 1085 (D.C. Cir. 1986) (en banc)). Thus, I am not required to ignore this evidence in adjudicating the dispensing allegations.

[42] The record also contains a number other Dilaudid 8 mg prescriptions which were for quantities and dosages that exceeded the upper recommended dosage by nearly two fold or more. *See* GX 13, at 23 (168 du); 27 (240 du); and at 35 (196 du); GX 14, at 29 (168 du); 31(180 du); 33 (180 du); 35 (168 du); 37 (180 du); and 41 (180 du); GX 15, at 13 (180 du); 15 (168 du); 17 (180 du); 19 (168 du); 21 (168 du); 23 (168 du); and 25 (180 du). For the same reasons set forth in my discussion of the Dilaudid prescriptions filled by D.K. and G.C., I conclude that Respondent's pharmacists violated their corresponding responsibility when they filled these prescriptions. As for the remaining Dilaudid prescriptions, with the exception of the prescriptions dispensed to B.W. and T.F., I decline to address whether Respondent's pharmacists violated 21 CFR 1306.04(a) when they dispensed them.

[43] With respect to the Dilaudid 8 mg and methadone 10 mg prescriptions which Mr. George filled for T.F., Mr. Parrado identified, *inter alia,* the simultaneous prescribing of these two-short acting medications together and the dosing of the methadone (2 tablets in the morning, one at bedtime) as raising concerns over the legitimacy of the prescriptions. Of note, on the back of each prescription, there are notations dated "1/21/13" (the same day the prescription was filled), as well what appears to be "ILKA," and "Director—Operation." Mr. George did not, however, explain the meaning of the notations.

[44] There were also prescriptions for quantities ranging from 180 du to 210 du. *See generally* GX 3.

As for the issue of whether Mr. George conclusively resolved that the prescriptions were issued for a legitimate medical purpose, as previously explained, Mr. George offered only his generalized and not credible testimony that he always checked the patient profiles and did his due diligence and failed to specifically address how he resolved any of these other prescriptions. That, plus Respondent's failure to produce the purported due diligence checklists to corroborate his testimony, support the adverse inference that he failed to do so. I therefore find that Respondent's pharmacists violated 21 CFR 1306.04(a) when they dispensed numerous other oxycodone prescriptions.[45]

While I conclude that the quantities and dosing of these prescriptions alone support a finding that there was a high probability that the oxycodone prescriptions lacked a legitimate medical purpose, Mr. Parrado also identified another red flag—the high prices Respondent charged for the oxycodone prescriptions and the fact that patients were paying for them in cash or cash equivalents. Tr. 71–72, 75–76, 87–89, 112, 132–33, 165. As the evidence shows, the price Respondent charged for a 180 du prescription ranged from $675 in April 2011 to $1350 in in December 2012, and many of the prescriptions costs $800 or more. GX 3, at 1, 3, 5,11,15,17, 20, 24, 26, 28, 29, 30, 34, 35. As Mr. Parrado explained with respect to a prescription for 196 du which, at that time, cost $784:

> You don't see people paying $784 in cash. You tell a person they have a $50 co-pay and they go ballistic on you. And for a person to willingly pay $784 and not have any documentation as to why they did that and to see that over and over every day is a concern to me. . . . That's a red flag I couldn't resolve.

Tr. 71. And when asked on cross-examination if he had ever filled a prescription for someone who did not have insurance, Mr. Parrado answered that he was not going to give "a yes or no answer because . . . a person who . . . can't afford insurance . . . is not going to pay 1,200 or 1,300 for a prescription." *Id.* at 132.

Notably, Mr. Badawi offered no testimony refuting Mr. Parrado's testimony that the cost of the prescriptions was also a red flag. Indeed, were these patients legitimate chronic pain patients, they would presumably require oxycodone on a monthly basis and would have spent $7,000 to $10,000 a year for this medication in 2011 (when Respondent's prices were lowest) and thousands more the following year.[46] This evidence further supports the conclusion that Respondent's pharmacists either knew that the prescriptions lacked a legitimate medical purpose or subjectively believed that there was a high probability that the prescriptions were illegitimate and deliberately failed to investigate further.

Against this evidence, Respondent points to the changes it made in its due diligence procedures after the AIW was served, the data it submitted showing that it has substantially decreased its dispensing of controlled substance prescriptions, and its decision—made three weeks before the hearing—to stop dispensing controlled substance prescriptions issued from pain management clinics. While Mr. George explained that he made these changes because "[a]s a professional provider," he had "a part to do to prevent the abuse and misuse and diversion of . . . controlled substances," even were I to accept his testimony as true, it does not outweigh the substantial evidence that he and Respondent's other pharmacists violated their corresponding responsibility and knowingly diverted controlled substances. 21 CFR 1306.04(a).

Other Allegations

The Government also alleged that Respondent violated various recordkeeping provisions of the CSA and DEA regulations. The allegations included that Respondent: (1) Had failed to complete a biennial inventory, (2) did not notate on its schedule II order forms the date and quantity it received of schedule II drugs, (3) failed to retain Copy 3 of its order forms, and (4) its records were not readily retrievable. The Government further points to the results of an audit it conducted which found multiple overages and a shortage of schedule II drugs.

The Availability of Respondent's Records

The Government alleged that Respondent "failed to maintain records of [s]chedule II prescriptions, inventory records, and receiving records . . . in a readily retrievable form at its registered location in violation of 21 CFR 1304.04(a) and (h)(2)." ALJ Ex. 1, at 4 As found above, a DI testified that Respondent was not able to provide all of the records when the AIW was executed, specifically the prescriptions from February 4, 2011 through April 2011, the inventories from February 4, 2011 through the end of 2011, and the receiving records from February 4, 2011 through the end of 2011. Tr. 252. According to the DI, he personally witnessed an attorney for Respondent state that the records were offsite and that the office manager had the key but was not available that day. *Id.* at 253.

Reasoning that the attorney's statement was hearsay, the ALJ specifically found credible Mr. George's testimony that the records were locked in a storage room at the back of the pharmacy but that he did not have the key to the room on the date that the AIW was executed. R.D. at 45 n.30. While Mr. George testified that Respondent's owner showed up with the key within a couple of hours but after the Investigators had left, the Government put forward no evidence as to how long the Investigators were on the premises.

Under generally applicable regulations, except as otherwise provided, "every inventory and other records required to be kept under [21 CFR 1304] must be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration." 21 CFR 1304.04(a). Under the regulation applicable to a pharmacy, "[i]nventories and records of all controlled substances in Schedule . . . II shall be maintained separately from all other records of the pharmacy." 21 CFR 1304.04(h)(1).

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[45] I do not adopt a categorical rule as to the distance a patient must have travelled to render a controlled substance prescription suspicious. Distance is just one of the factors that a pharmacist must evaluate, and while a patient's willingness to travel a long distance to obtain a prescription is highly suspicious, a patient who seeks drugs for other than legitimate medical purposes may live in the same city as the prescriber and/or pharmacy. Indeed, several of the patients who lived in Tampa presented prescriptions for such quantities of oxycodone 30 as 168 du, 180 du, 210 du, and 224 du. *See* GX 3, at 18, 19, 26, and 35.

[46] I do not adopt the Government's contention that the prescriptions also presented the red flag of pattern prescribing. At most, the Government identified 10 prescriptions for oxycodone 30 that were written by physicians from 24th Century and filled by Respondent on the same day—April 21, 2011. GX 3, at 16–25. Notably, the prescriptions ranged in dosage from 140 to 240 tablets. *See id.* Moreover, another Government Exhibit refutes this contention as it includes twenty prescriptions written by doctors from the 24th Century clinic and filled by Respondent from April 14 through April 20, 2011. *See generally* GX 13. Notably, the exhibit includes four prescriptions for oxycodone 30, nine prescriptions for Dilaudid (some in the 4 mg tablet, others in the 8 mg), and 7 prescriptions for MS Contin (some in 30 mg tablet, others in 60 mg). *See id.*

As the evidence shows, when the Government obtained Respondent's records, it took only the schedule II prescriptions and provided only these prescriptions to Mr. Parrado. Notably, during the period of 2011 through early 2013, combination hydrocodone drugs, which are among the most highly prescribed drugs overall and are prescribed for pain, were in schedule III of the CSA, and any such prescriptions were not provided to Mr. Parrado. So too, Mr. Parrado was not provided with the prescriptions, if any, written by the 24th Century doctors for other drugs they may have prescribed for pain such as Tylenol with codeine (also in schedule III), pregabalin (Lyrica, schedule V), as well as non-controlled medications such as ibuprofen and naproxen. Thus, there is no basis to conclude that the 24th Century doctors were engaged in pattern prescribing.

As to the schedule II order forms, "[t]he purchaser must retain Copy 3 of each executed DEA Form 222" and the forms "must be maintained separately from all other records of the registrant" and "be kept available for inspection for a period of two years" at the registered location. *Id.* § 1305.17(a) & (c). Moreover, "[p]aper prescriptions for Schedule II controlled substances shall be maintained at the registered location in a separate prescription file." 21 CFR 1304.04(h)(2).[47] Unlike the provision applicable to prescriptions in schedules III though V, this provision does not authorize the maintenance of schedule II prescriptions "in such form that they are readily retrievable from other prescription records of the pharmacy." 21 CFR 1304.04(h)(4). Indeed, none of the above regulations allows for these records to be kept with other records of the pharmacy as long as they are "readily retrievable from [those] other" records.

In the Order to Show Cause, the Government nonetheless alleged that Respondent "failed to maintain records . . . in a readily retrievable form at its registered location." ALJ Ex. 1, at 4. I find the violation proved. As explained above, the ALJ reasoned that the attorney's statement was hearsay and therefore gave it less weight than Mr. George's testimony. However, contrary to the ALJ's understanding, the attorney's statement was not hearsay because it was an admission of a party-opponent. *Cf.* Fed. R. Evid. R. 801(d)(2). Attorneys typically do not make admissions on behalf of clients to Government investigators without a factual basis for doing so.[48] Moreover, the attorney's statement was made contemporaneously with the inspection, unlike Mr. George's testimony which was offered well after fact and during a proceeding in which he had ample motive to misstate the facts. Accordingly, I find that various records including some of the schedule II prescriptions and schedule II order forms were not kept on the premises of Respondent's registered location as required by federal regulations.

The Allegations That Respondent Failed To Complete a Biennial Inventory

According to the DI, during the inspection, Respondent produced a document for the audited drugs on which it kept a perpetual inventory, *i.e,* a running total of the balance on hand listed by the date of various transactions. Specifically, the log listed: (1) The results of inventories which were actual "physical count[s] of what was on hand," Tr. 270; (2) dispensings by prescription number and the quantity dispensed; (3) the quantities received by each order form number and invoice numbers; and (4) returns by patients. GX 5. According to the DI, the inventories did not comply with federal law because "there was not one date [when] every controlled substance was inventoried." Tr. 235.

More specifically, the records showed that methadone 10 was inventoried on January 2, 2012. GX 5, at 1. While morphine sulfate 30 mg immediate release and morphine sulfate 100 m extended release were inventoried on January 2, 2012, morphine sulfate 60 mg extended release was inventoried on January 3, 2012, and morphine sulfate 30 mg extended release was not inventoried until June 9, 2012. GX 5, at 2–5. As for hydromorphone 8 mg, the only inventory listed is one taken on July 24, 2012, and while an inventory of Dilaudid 4 mg was taken on January 2, 2012, the sheet for generic hydromorphone 4 mg lists an inventory date of June 6, 2012 and the quantity on hand as "-4" while also including the undated notation of "60" in the header for the "balance" column. *See id.* at 6–8. Finally, the sheet for oxycodone 30 lists the inventory date as June 27, 2012, yet there is also an undated entry in the header for the "balance" column with the notation of "1030"; the sheet also lists multiple prescriptions, a receipt from a distributor and what appears to be a return from a patient. *Id.* at 9.

Against this evidence, Respondent introduced an exhibit which purports to be an "Annual Inventory" of its schedule II controlled substances which was taken on January 2, 2012 and which lists Mr. George as its pharmacist. *See* RX 4. Asked on cross-examination whether he had seen this document before, the DI answered "no," and testified that the document was not provided to the Government during the execution of the AIW. Tr. 276. Respondent, however, points to a Florida Department of Health Inspection Report which states that during a September 14, 2012 inspection, the State Investigator found that Respondent had taken a controlled substance inventory on a biennial basis and that the inventory was available for inspection; the report also noted that "[t]he most recent Biennial Inventory is dated 01–02–12." RX 4, at 6.

The ALJ surmised that at the time of the AIW, either the DI did not request the biennial inventory or that Respondent's personnel did not understand the request. R.D. at 8–9 n.3. Nor does the record establish why this document was not turned over pursuant to the AIW (the AIW not being in the record either) with the documents that were subsequently turned over by Respondent's attorney. In any event, I find the evidence insufficient to support the allegation that Respondent failed to complete a biennial inventory as required by 21 CFR 1304.11(c). ALJ Ex. 1, at 4.

Allegations Related to Respondent's Maintenance of Its Schedule II Order Forms

The Government also alleged that Respondent's manner of keeping its schedule II order forms violated DEA regulations in two respects. First, it alleges that Respondent failed to document on the forms the "receipt date or quantity received." *Id.* (citing 21 U.S.C. 827(b); 21 CFR 1305.13(e)). Second, it alleges that Respondent failed to retain Copy 3 of the order form. *Id.* (citing 21 U.S.C. 827(b); 21 CFR 1305.13(a) and 1305.17(a)).

As support for the allegations, the Government submitted copies of 11 "purchaser's Copy 3" of order forms Respondent submitted to various distributors. Under DEA's regulation, "[t]he purchaser must record on Copy 3 . . . the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser." 21 CFR 1305.13(e). However, under another DEA regulation, an order form is not valid "more than 60 days after its execution by the purchaser.'' *Id.* § 1305.13(b).

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[47] While invoices (but not schedule II order forms) "may be kept at a central location, rather than the registered location," to do so, a registrant must notify the Special Agent in Charge in writing "of [its] intention to keep central records." 21 CFR 1304.04(a)(1). While the DI subsequently identified GX 10 (which contain only schedule II order forms as containing receiving records, it is otherwise unclear whether the DI's reference to receiving records also included the invoices. *See, e.g.,* GX 11. As to the invoices, there is no evidence in the record as to whether Respondent ever notified the Agency of its intent to keep records at other than its registered location.

[48] According to the DI, some of the Investigators attempted to interview Mr. George, but shortly into the interview, the attorney arrived and did not allow the Investigators to speak with Mr. George or any another employees and "[a]ll questions were to be directed through [the attorney] at that point." Tr. 283. Thus, the attorney clearly acted as Respondent's authorized representative and made the statement that the missing records were offsite within the scope of his relationship with Respondent.

With respect to the 11 order forms, each of the forms includes notations indicating one or more items was filled by the supplier, with a handwritten notation as to the number of packages received, the date of receipt, and initials. *See generally* GX 10. Two of the order forms contain a notation that a number of packages were received but no entry for the date the package was received. *Id.* at 9 (entry for methadone 10); *id.* at 11 (line no. 1—indicating 12 packages of hydromorphone 8 were received but leaving blank the date received). Respondent thus violated 21 CFR 1305.13(e) by failing to notate the date these two packages were received.

The order forms also included line items that were not filled in any part by the supplier, and the forms were left blank in the columns for ''No. of Packages Received'' and ''Date Received.'' *See generally* GX 10. According to the DI, when Respondent did not ''receive a drug,'' it was required ''to write a zero'' in the column for the number of packages received. Tr. 255. The DI was, however, unsure if Respondent was required to also include a date. *Id.* at 256.

As to this contention, DEA regulations do not require a purchaser to notate on the order form that no portion of a particular item was received and a date. *See* 21 CFR 1305.13(e). Accordingly, to the extent this allegation relies on Respondent's failure to notate and date the non-receipt of items it ordered, the allegation is rejected.[49]

As for the allegations that Respondent ''failed to retain Copy 3 of the'' order forms, the Government proof was comprised of a single 222 form which, according to the DI, was a xerox and not the original Copy 3. GX 11, at 2. This is a violation, as under 21 CFR 1305.17(a), ''[t]he purchaser must retain Copy 3 of each executed DEA Form 222.'' However, this violation, as well as the two other violations based on Respondent's failure to notate the date on which the packages were received, are of minor consequence.[50]

The Audit Allegations

The Government also put forth evidence that it conducted an audit of Respondent's handling of seven controlled substances and found that it had overages in six drugs and a shortage in one drug. With respect to the latter, the audit found that Respondent was short 4,135 du of hydromorphone 4 mg. With respect to the overages, as alleged by the Government, the most significant were those of 8,758 du of hydromorphone 8 mg and 1,306 du of oxycodone 30 mg.

''Recordkeeping is one of the CSA's central features; a registrant's accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances.'' *Paul H. Volkman,* 73 FR 30630, 30644 (2008); *see also Fred Samimi,* 79 FR 18698, 18712 (2014) (finding, where physician ''had shortages totaling more than 40,000 dosage units'' of various drugs, that his ''inability to account for this significant number of dosage units creates a grave risk of diversion,'' and that ''even were there no other proven violations, the audit results alone are sufficient to . . . establish[ ] that [physician's] registration[ ] 'would be inconsistent with the public interest' '') (citations omitted).

Respondent raises a variety of challenges to the audit results. First, it asserts that the audits were flawed because they used figures from Respondent's perpetual inventory for the initial inventory rather than the inventory they produced at the hearing but had not provided to the Government previously. Resp. Exceptions, at 4. It further asserts that ''[h]ad DEA started with the record that the Agency actually requires registrant to keep . . . . (the biennial inventory), DEA would have had to use all of Respondent's records of receipt and dispensing during 2012, and DEA would not have found the alleged overages and shortages that its investigators claimed to find.'' *Id.*

Yet the Investigator testified repeatedly that the so-called perpetual inventory is all that Respondent provided to him. Most significantly, the Investigator testified that Mr. George ''stated that every line marked inventory was a physical count of what was on hand.'' Tr. 270. I therefore find no basis to reject the audit result because the Government used the physical counts listed on the perpetual inventory.

As for the Government's audit of the hydromorphone 4 mg, Respondent produced a listing by date, prescription number, and the quantity dispensed for the period of July 30, 2012 through February 4, 2013. *See* RX 5, at 2–3. Notably, each of the dispensings corresponds with the dispensings listed in the perpetual inventory and both documents show that Respondent dispensed a total of 4,659 du during the audit period, a figure which is 120 dosage units less than that determined (4,779) by the Government.[51] *See* GX 4. The effect, however, is that Respondent's shortage was even larger than that found by the Government. As for the closing inventory figures, while Respondent argues that I should reject the Government's figures because Mr. George did not attest to the accuracy of the figures (*see* Resp. Exceptions at 8–9, Resp. Post-Hrng Br. at 53), the difference between the Government's count (202) and Respondent's (200) was two (2) tablets, a difference of inconsequence.

By contrast, there is a substantial difference between the figures the Government and Respondent calculated for Respondent's receipts during the audit period. According to the Government, Respondent acquired 7,900 tablets during the period; according to Respondent, it acquired only 3,900 tablets. Compare GX 4 *with* RX 5, at 1.

This disparity is explained, however, by the Government's identification of an additional transaction on January 28, 2013, when Respondent acquired 4,000 du from Nucare Pharmaceuticals. GX 6, at 8. Notably, this transaction does not appear on Respondent's list of its acquisitions. *Compare id. with* RX 5, at 1. Significantly, Respondent put forward no evidence refuting the Government's finding that the transaction occurred or that Respondent had received the drugs as of the date of the AIW. Thus, not only do I find no reason to reject the Government's finding with respect to Respondent's handling of hydromorphone 4 mg, I find that the shortage was even larger than alleged by the Government.[52]

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[49] The Government put forward no evidence with respect to any of the order forms that Respondent had actually received any of the drugs listed in the line items which were left blank.

[50] Invoking a DEA regulation which grants the ALJ ''all power necessary'' to conduct a fair hearing, Respondent apparently argues that I should give no weight to the Government's documentary evidence, because following the execution of the AIW, the Investigators ''illegally retain[ed] the documents for 611 days'' and ''never provided a meaningful accounting of the documents seized.'' Resp. Exceptions, at 16. As Respondent further argues:

> ''To give any weight to the DEA's documentary evidence would be tantamount to sanctioning the unlawful conduct of the investigators and would work a great procedural and substantive injustice on Respondent. The only fair action (thus, a ''necessary action'') is to give no weight to the DEA's documentary evidence and to give no weight to the testimony about those documents.''

Id. at 18.

In its Exceptions, Respondent does not identify a single allegation that it has been unable to respond to because of the Government's delay in returning the documents or its failure to provide a meaningful accounting of the documents. Because Respondent has failed to establish prejudice, I reject its claim. *See Air Canada* v. *Department of Trans.,* 148 F.3d 1142, 1156 (D.C. Cir. 1998) (''As incorporated into the APA, the harmless error rule requires the party asserting error to demonstrate prejudice from the error.'') (citing 5 U.S.C. 706).

[51] Respondent's perpetual inventory shows that an inventory was taken on July 24, 2012 of its stock of hydromorphone 4 mg, and that 1096 tablets were on hand; it also shows that Respondent did not dispense a prescription for the drug until July 30, 2012. RX 5, at 4. The evidence also shows that Respondent maintained a separate perpetual inventory log for Dilaudid (branded hydromorphone) 4 mg. GX 5, at 8. The log has only three entries; the entries provide inventory figures for January 2, 2012, June 9, 2012, and December 31, 2012. *See id.* On each date, Respondent had 120 tablets in stock. This figure, when added to the July 24, 2012 inventory for hydromorphone of 1096, equals 1216, the same figure which the Government used as its initial inventory.

As for the overage in hydromorphone 8 mg, Respondent disputed the Government's figure for the amounts received, the quantities distributed or dispensed, and the closing inventory. With respect to the amounts received, both the Government and Respondent provided a list of the shipments by date, order number, distributor's name, and quantity. Notably, Respondent's list includes four shipments which are not on the Government's list.

The first of these is an order purportedly filled by Harvard Drug on November 11, 2012 for 400 du pursuant to Order Form #121140458. RX 6, at 1. The order is, however, unsupported by an invoice, and notably, while Respondent submitted a copy of Order Form #121140458, that form was used to place an order with a different distributor, Red Parrot Distribution. *See id.* at 1; *see also id.* at 78, 80, 84 (invoices for the shipments received from Red Parrot on 11/17, 11/15, and 11/21/12); *id.* at 85 (DEA Form 222 #12114058). I thus find that Respondent did not receive 400 du from Harvard on November 11, 2012.

Respondent's list of receipts also includes shipments received from Attain Med on December 19 and 24, 2012, each of which was for 2,400 du, pursuant to Order Form #12x00003. RX 6, at 1. Respondent provided a copy of the order form and the invoices for each shipment. *Id.* at 92 (Order Form #12xx00003); *id.* at 91 (invoice for 24 packages shipped on 12/18/12 under same Order Form Number); *id.* at 90 (invoice for 24 packages shipped on 12/24/12 under same Order Form Number). The Government's list includes, however, only the first shipment for 2,400 du. GX 6, at 6. I therefore find that Respondent received both shipments and that the second shipment should have been credited by the Government.

Respondent's list also included two receipts of 2,500 du totaling 5,000 du from Nucare Pharmaceuticals pursuant to Order From #121140485. RX 6, at 1. According to the Government's list, Respondent received only one of these shipments. GX 6, at 6. Respondent, however, produced both a Form 222 (dated 12/17/12) which is annotated to reflect both shipments by date and quantity, as well as two invoices documenting its receipt of 5,000 du from Nucare pursuant to Order Form #121140485. *See* RX 6, at 97 (Form 222); *id.* at 96 (01/15/13 invoice for second shipment of 2500 du under Order #121140485); *id.* at 118 (12/26/12 invoice for first shipment of 2500 du under Order #121140485). I therefore find that Respondent received an additional 2,500 du pursuant to this order than was credited by the Government.

Respondent also listed a receipt of 2,400 du from Attain Med on January 19, 2013, pursuant to Order Form #13XX00001, RX 6, at 2; this shipment is not included on the Government's list. *See* GX 6, at 6–7. While Respondent did not produce the Order Form, it did produce an invoice showing that 2,400 du were shipped to it on January 19, 2013 pursuant to the aforesaid Order Form number and should have been credited by the Government. RX 6, at 102.

Finally, while the Government's list includes an order for 4,000 du which was filled by Nucare and received by Respondent on January 28, 2013 pursuant to Order Form #121140486,[53] Respondent's list also includes a shipment for 1,000 du pursuant to the same order form which it received on January 29, 2012. RX 6, at 2. While Respondent did not produce the order form, it did produce invoices for both shipments. RX 6, at 105–06. Thus, the additional 1,000 du should have been credited by the Government.

However, the Government also credited Respondent as having received two orders for 800 du each from Red Parrot on February 1, 2012 pursuant to Order Form #121140488. GX 6, at 7. Notably, while the DEA Form 222 shows that on January 29, 2013, Respondent ordered a total of 4,800 du, on the Order Form (as well as in his Perpetual Inventory), Respondent documented the receipt of only 800 du on February 1, 2013, an amount consistent with the invoice. *See* RX 6, at 108 (Form 222); *id.* at 107; *id.* at 37. According to Respondent's perpetual inventory, it did not receive an additional shipment from Red Parrot for hydromorphone 8 mg until February 6, 2013, after the closing date of the audit. *See id.* at 38. Thus, I have excluded this amount in calculating Respondent's receipts.

I therefore find that Respondent actually received an additional 7,500 du from its distributors than the amount calculated by the Government.[54] Moreover, the Government did not include the 433 du which were returned by the patients. Thus, Respondent was accountable for a total of 75,333 du.

As for the dispensings, the Government calculated the total at 71,759 du, Respondent at 72,195. Respondent's figure, however, includes six prescriptions totaling 858 du which were dispensed on February 4, 2013, the date of the AIW. RX 6, at 16–17. The Government's evidence shows, however, that the closing inventory was taken at the beginning of business, and thus these prescriptions are not properly included in the audit period. GX 7; Tr. 237. Thus, according to Respondent's data, its total dispensings during the audit period were 71,337 du, a difference of 422 du from the Government's figure.

The disparity is explained by five prescriptions, four of which are listed on the Government's list (GX 8, at 8–18) but not on Respondent's list (RX 6, at 4–17), as well as one prescription which is listed on Respondent's list but not the Government. More specifically, the Government's list includes: (1) RX #2039300 for 140 du (*compare* GX 8, at 8, *with* RX 6, at 5); (2) RX #2039764 for 150 du (*compare* GX 8, at 13, *with* RX 6, at 11); (3) RX #2039782 for 84 du (*compare* GX 8, at 13, *with* RX 6, at 11); and (4) RX#2039952 for 168 du (*compare* GX 8, at 16, *with* RX 6, at 14); Respondent's list includes RX#2039243 for 120 du (*compare* RX 6, at 4, *with* GX 8, at 8).[55] The four prescriptions on the Government's lists (which total 542 du) and the prescription on Respondent's list (120 du) thus account for the 422 du disparity in the dispensings (after subtracting out Respondent's post-audit dispensings).

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[52] Respondent also challenges the audit results, arguing that the Investigator "did not account for any controlled substances in the pharmacy's will-call bin, returns to stock, or those drugs quarantined for disposal." Resp. Post-Hrng. Br. 52; *see also* Resp. Exceptions at 5–6. It further argues that under the Agency's regulation, "when conducting an inventory, the pharmacy must account for all controlled substances on hand at the pharmacy at the time of the inventory." *Id.* (citing 21 CFR 1304.11(a)).

As for Respondent's contention that the Agency was required to count the drugs in the "will-call bin," by implication the regulation does not require counting these drugs. *See* 21 CFR 1301.11(a) ("Controlled substances shall be deemed 'on hand' if they are . . . ordered by a customer but not yet invoiced[.]"). Notably, those drugs in the "will-call bin" have a dispensing label attached and are otherwise accounted for as having been dispensed, even if the customer has yet to pick up the prescription.

As for Respondent's contention that the Government did not include those drugs that were returned to stock, where Respondent produced such documentation, I have considered the returns. Finally, Respondent produced no evidence that at the time the Investigators took the closing inventory, it had in its possession any dosage units of the drugs being audited that were quarantined for disposal.

Finally, Respondent argues that the DI "willfully chose to ignore" evidence in its ARCOS database regarding its purchases of schedule II drugs, apparently because he did not obtain Respondent's complete ARCOS data and compare it with his calculations. Resp. Exceptions, at 18. There is, however, no requirement that the Government obtain ARCOS data, which is not submitted by pharmacies but rather distributors and is thus dependent upon the accuracy of their submissions, and indeed, one of the purposes of doing an audit is to determine whether the registrant being audited is maintaining complete and accurate records. In any event, as I have carefully reviewed Respondent's invoices and credited Respondent for those receipts which were supported by its records but were omitted by the Government, this argument is moot.

[53] While the Government lists the Order Number as 121140497, GX 6, at 6; Respondent listed it as 121140486, which corresponds with the invoices. RX 6, at 2, 105–06.

[54] While this may have been caused by Respondent's failure to provide the records pursuant to the AIW, it may also have been caused by mistakes made by the Investigator who prepared the audit. The record does not, however, allow me to make a determination either way.

As for the closing inventory figures, the Government put forward evidence that Respondent had 5,114 du on hand at the beginning of business, which included 48 full 100 count bottles and 314 other du. GX 7. Respondent asserted that it had on hand 4,086 du; however, this figure appears to have been determined after Respondent dispensed six prescriptions totaling 858 du on February 4, 2013. RX 6, at 17. Adding back in the 858 units Respondent represents that it dispensed on that date, yields a total of 4,944 du. And adding the 71,337 du Respondent represented that it had dispensed to its closing inventory figure of 4,944 du yields a total of 76,281 dosage units, this being the total Respondent accounted for. This compares with the total of Respondent's opening inventory, its receipts (including both its purchases and the dosage units returned by patients) of 75,333.

Thus, even using Respondent's figures for its receipts, dispensings, and closing inventory, it still had an overage of 948 dosage units. While this is substantially less that the figure calculated by the Government, it is still material and supports a finding that Respondent did not maintain complete and accurate records as required by 21 U.S.C. 827(a).

As for the audit's finding that Respondent had an overage of 1,306 du of oxycodone 30, GX 4, Respondent disputed the Government's finding that it received 17,200 du during the audit period. Instead, it put forward evidence that it received 18,300 du from distributors during the period and a comparison of the orders compiled by the Government with the orders compiled by Respondent shows that it placed two orders which totaled 1,100 du that were not included in the Government's count. More specifically, the Government's count did not include an order filled by PD–RX for 500 du on September 12, 2012 (Order Form Number 12X000019), and an order for 600 du filled by Attain Med on December 5, 2012. *Compare* GX 6, at 9, *with* RX 7, at 1. Moreover, Respondent provided the invoices to support its receipt of each order. *See* RX 7, at 40–41; *id.* at 87. Including the 12 dosage units that were returned by a customer, Respondent received a total of 18,312 dosage units during the audit period.

Notably, Respondent's Narcotic Control Sheet (RX 7, at 1) lists the same beginning count as the Government used (39 du), and the parties agreed that Respondent dispensed 18,322 du during the audit period. Including the orders that the Government did not include, Respondent was accountable for 18,351 du during the audit period and subtracting out the dispensings, should have had on hand 29 tablets at the time of the closing inventory. While Respondent's Narcotic Control Sheet lists the results of a physical inventory which was purportedly conducted on February 4, 2013 as 35 du (the same figure listed on Respondent's Perpetual Inventory as of February 4, 2013), this figure cannot possibly be accurate because on January 30, Respondent received an order of 300 du and its records show that it had only dispensed a single prescription for 140 du prior to the execution of the AIW and thus should have had at least 160 tablets on hand when the closing inventory was taken.[56] Thus, I find that the Government's closing inventory figure of 223 du is accurate and that Respondent had an overage of 194 du. While this overage is substantially smaller than that alleged by the Government, Respondent offered no explanation for the overage.

Sanction

Where, as here, "the Government has proved that a registrant has committed acts inconsistent with the public interest, a registrant must '"present sufficient mitigating evidence to assure the Administrator that it can be entrusted with the responsibility carried by such a registration."'" *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008) (quoting *Samuel S. Jackson,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller,* 53 FR 21931, 21932 (1988))). "Moreover, because 'past performance is the best predictor of future performance,' *ALRA Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir.1995), [DEA] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for its actions and demonstrate that it will not engage in future misconduct." *Medicine Shoppe,* 73 FR at 387; *see also Jackson,* 72 FR at 23853; *John H. Kennedy,* 71 FR 35705, 35709 (2006); *Prince George Daniels,* 60 FR 62884, 62887 (1995). *See also Hoxie* v. *DEA,* 419 F.3d at 483 ("admitting fault" is "properly consider[ed]" by DEA to be an "important factor[]" in the public interest determination).

The Agency has also repeatedly held that the level of candor exhibited by a registrant's principals during "the hearing itself is an important factor to be considered in determining both whether [it] has accepted responsibility as well as for the appropriate sanction." *Michael S. Moore,* 76 FR 45867, 45868 (2011); *see also Robert F. Hunt,* 75 FR 49995, 50004 (2010); *Jeri Hassman,* 75 FR 8194, 8236 (2010); *Hoxie,* 419 F.3d at 483 ("Candor during DEA investigations, regardless of the severity of the violations alleged, is considered by the DEA to be an important factor when assessing whether a . . . registration is consistent with the public interest.").

Nor are these the only factors that are relevant in determining the appropriate sanction. *See, e.g., Joseph Gaudio,* 74 FR 10083, 10094 (2009); *Southwood Pharmaceuticals, Inc.,* 72 FR 36487, 36504 (2007). Obviously, the egregiousness and extent of a registrant's misconduct are significant factors in determining the appropriate sanction. *See Jacobo Dreszer,* 76 FR 19386, 19387–88 (2011) (explaining that a respondent can "argue that even though the Government has made out a *prima facie* case, his conduct was not so egregious as to warrant revocation"); *Paul H. Volkman,* 73 FR 30630, 30644 (2008); *see also Paul Weir Battershell,* 76 FR 44359, 44369 (2011) (imposing six-month suspension, noting that the evidence was not limited to security and recordkeeping violations found at first inspection and "manifested a disturbing pattern of indifference on the part of [r]espondent to his obligations as a registrant"); *Gregory D. Owens,* 74 FR 36751, 36757 n.22 (2009).

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[55] Respondent's Perpetual Inventory included entries for RX#2039300 and RX#2039782. RX 6, at 20, 29. As for RX#2039300, the Perpetual Inventory included the notation "wrong" with a line drawn through the prescription number, the date, the quantity, and Mr. George's initials. RX 6, at 20. Respondent did not, however, add back in the quantity to the balance. *Id.* As for RX#2039782, the entry states "voided" to the left of the prescription number. *Id.* at 29. The record contains no further evidence establishing whether these prescriptions, or the other two prescriptions which were on the Government's list but not Respondent's, were actually dispensed.

[56] Given the impossibility that Respondent's closing inventory figure is accurate, and the Government's evidence that two investigators counted the oxycodone 30, I find the Government's inventory figure to be accurate.

However, Respondent argues that because Mr. George did not participate in counting the drugs for the closing inventory, "the Government violated its own credibility safeguards." Resp. Exceptions at 6; *see also id.* at 4 (noting that this approach "was contrary to the agency's internal guidance and customary practice") (citation omitted). Even so, two Agency employees counted the drugs and vouched for the accuracy of the counts. Thus, while I do not condone the Investigators' failure to have Mr. George participate—at least in the absence of evidence that Mr. George was unwilling to do so—I nonetheless find no reason to conclude that the closing inventory figures found by the Government were unreliable.

The Agency has also held that "'[n]either *Jackson,* nor any other agency decision, holds . . . that the Agency cannot consider the deterrent value of a sanction in deciding whether a registration should be [suspended or] revoked.'" *Gaudio,* 74 FR at 10094 (quoting *Southwood,* 72 FR at 36504); *see also Robert Raymond Reppy,* 76 FR 61154, 61158 (2011); *Moore,* 76 FR at 45868. This is so, both with respect to the respondent in a particular case and the community of registrants. *See Gaudio,* 74 FR at 10095 (quoting *Southwood,* 71 FR at 36503). *Cf. McCarthy* v. *SEC,* 406 F.3d 179, 188–89 (2d Cir. 2005) (upholding SEC's express adoptions of "deterrence, both specific and general, as a component in analyzing the remedial efficacy of sanctions").

Here, the ALJ found that Mr. George did not credibly accept responsibility for Respondent's misconduct. R.D. at 52. The ALJ specifically noted Mr. George's testimony that "[a]s the pharmacist in charge . . . I accept the responsibility of conduct of the pharmacy. Again while I did all my due diligence and protocol, as I said before, still I'm less than perfect." *Id.* (citing Tr. 507). *See also* Tr. at 539–40 ("even though I did my best, our best to control that and prevent the abuse and misuse, that is not perfect. It is always less than perfect. Human beings are not perfect. I accept that responsibility."). Asking whether this was a sufficient acceptance of responsibility, the ALJ concluded that Mr. George was "still asserting that he had done all of his due diligence and had followed the Respondent's protocol" and that his "statement lacks credibility." R.D., at 52. And she also found that Mr. George's testimony that he had "always" done his due diligence lacked credibility.

I agree with the ALJ that Mr. George's testimony was not credible and that Respondent has not accepted responsibility. Indeed, much of Mr. George's testimony was contrived and other portions were plainly disingenuous.

Of particular note is Mr. George's testimony regarding the reason that Respondent filled the prescription (for 210 oxycodone 30) for T.V., who had traveled 472 miles from Pensacola. According to Mr. George, T.V. had been coming to Respondent since 2009 and the reason she was travelling this distance was because "she used to come and see that doctor [Dr. Ruperto] *always. And while I was interviewing that patient she said she likes the doctor and she wanted to continue seeing that doctor.*" Tr. 588 (emphasis added). Yet the prescription which the Government submitted into evidence was written by Dr. P.C., and was written more than two and a half years after Dr. Ruperto's death. Indeed, while Mr. George testified that T.V. had been coming to his pharmacy since 2009, Tr. 494, 579; Dr. Ruperto died in December 2008, before T.V. even began filling her prescriptions at Respondent. Yet Mr. George maintained that he had done all of his due diligence with respect to T.V.'s prescription.

So too, with respect to H.C., Jr., Mr. George testified that notwithstanding that he no longer had insurance and had not filled a prescription at Respondent for two years, he was "willing to pay whatever the cash price at that time" was for his oxycodone 30 prescription—$1350—because he "need[ed] this medication." Tr. 496–97. Mr. George thus stated that he "filled this prescription for cash." *Id.* at 497. Yet based on the progress note Mr. George obtained, he knew that at the same visit, H.C., Jr. had also been prescribed three other controlled substances, including 112 OxyContin 40 mg, 84 Xanax 1 mg, and 84 carisoprodol. While Mr. George denied knowing anything about drug cocktails, as Mr. Parrado testified, the combination of an opioid, benzodiazepine and carisoprodol was widely known for its abuse potential. RX 3, at 47. Also unexplained by Mr. George is how a patient, who had lost his insurance, would be able to pay $1350 a month, each month, for this one prescription alone, as would be expected if the patient was a legitimate chronic pain patient. Here too, I do not believe his testimony.

In still other instances, Mr. George gave inconsistent testimony. For example, Mr. George testified that he looked at the partial medical records as "an extra step to prevent the abuse and misuse of the controlled substances" and that "through experience, [he] learned to look through these forms and understand" them. Tr. 481. However, when asked with regard to patient S.D. whether he had reviewed the medical record before filling an oxycodone 30 prescription and if he could tell from the record what other controlled substances were dispensed that day, Mr. George testified that he "look[ed] only for my prescription which is received in my hand. That is only my concern." Tr. 561. He then added that "[i]f I get the medical record, I have no way of saying and understanding where the patient had a different prescription unless I talk to the patient or doctors if he write any other prescriptions. I cannot guess where the prescription was filled for that patient." [57] *Id.* Yet the progress note in S.D.'s file clearly showed that the physician had also prescribed four other controlled substances to S.D. at this visit, including MS Contin, Soma, Xanax, and Dilaudid. RX 3, at 29.

Mr. George then testified that in "looking [at] all these documents," he was "going above and beyond what the duty" of a pharmacist requires of him, and that "it is not [a] pharmacist's job to read, that is doctor's job." Tr. 561–62. To be sure, as Mr. Parrado explained, pharmacists usually do not obtain medical records in the course of dispensing. Tr. 599. Nonetheless, registrants (and their principals such as Mr. George) are not excused from ignoring the information they do obtain and one does not need a degree in medicine to read S.D.'s progress note and recognize that S.D. had been prescribed five different controlled substances at the same visit, including not only duplicative therapy in the form of two short-acting narcotics (oxycodone 30 and Dilaudid 8 mg), *see* Fla. Admin Code r.64B16–27.810, but also a drug cocktail well known to be abused on the street.

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[57] Mr. George, however, had also previously testified that under the protocol that was in place when he filled this prescription, "we check that they have narcotic contract with the patient." Tr. 450. *See also id.* at 458. Notably, one of the terms of S.D.'s narcotic contract was that "I will have prescriptions filled at only one pharmacy," and the contract then listed Superior (and not Respondent) as the only pharmacy. RX 3, at 30–31. Certainly, Mr. George knew from the progress note what other prescriptions were written on that date and whether they were being presented at Respondent for filling. Apparently, it was not a concern that S.D. was filling the prescription at his pharmacy, rather than the pharmacy listed on his narcotic contract.

At another point, Mr. George testified that "[f]rom 2013 onwards," he had "modified [his] protocol and changed it to print out patient's residence to less than 15 miles," Tr. 499, thus suggesting (although there is an argument that his answer was incoherent) that he would no longer fill the prescriptions if the patient lived more than 15 miles away. Yet he later testified that after DEA executed the AIW (on Feb. 4, 2013), he changed the protocol to fill only for patients who lived within 50 miles. *Id.* at 570–71.

I thus agree with the ALJ that Mr. George, as Respondent's principal, has not adequately accepted responsibility for its misconduct. This finding provides reason alone to conclude that Respondent has not rebutted the Government's *prima facie* showing that it has committed acts which render its continued registration "inconsistent with the public interest." 21 U.S.C. 824(a)(4). And having found that Mr. George and Respondent knowingly diverted controlled substances, there is no need to consider Respondent's remedial efforts as they are rendered irrelevant by its failure to acknowledge its misconduct. *See The Medicine Shoppe*, 79 FR 59504, 59510 (2014), *pet. for rev. denied* 626 Fed. Appx. 2 (Mem.) (D.C. Cir. 2015); *Jayam Krishna-Iyer*, 74 FR 459, 464 (2009) ("Because of the grave and increasing harm to public health and safety caused by the diversion of prescription controlled substances, even where the Agency's proof establishes that a practitioner has committed only a few acts of diversion, this Agency will not grant or continue the practitioner's registration unless he accepts responsibility for his misconduct."). As the Tenth Circuit has recognized in the context of physician practitioners:

> The DEA may properly consider whether a physician admits fault in determining if the physician's registration should be revoked. When faced with evidence that a doctor has a history of distributing controlled substances unlawfully, it is reasonable for the [DEA] to consider whether that doctor will change his or her behavior in the future. And that consideration is vital to whether continued registration is in the public interest.

MacKay v. *DEA*, 664 F.3d 808, 820 (10th Cir. 2011) (citing *Hoxie* v. *DEA*, 419 F.3d at 483 (6th Cir. 2005)). See also *Hoxie*, 419 F.3d at 483 ("The DEA properly considers the candor of the physician . . . and admitting fault [to be] important factors in determining whether the physician's registration should be revoked.").

I further find that the misconduct proven on this record is egregious and supports the revocation of Respondent's registration. More specifically, my finding that Respondent's pharmacists dispensed multiple prescriptions in violation of their corresponding responsibility and thereby knowingly diverted controlled substances is, by itself, sufficient to support the revocation of its registration. Revocation is also warranted by my finding that Respondent was short more than 4,000 du of hydromorphone 4 mg. And I also find that revocation is supported by Mr. George's lack of candor during his testimony.

I further find that the Agency's interest in deterring future misconduct both on the part of Respondent (and Mr. George) as well as the community of pharmacy registrants supports revocation. As for the issue of specific deterrence, the revocation of Respondent's registration is not a permanent bar, and as to Mr. George, because pharmacists are not required to be registered under the CSA, revocation is warranted to deter Mr. George from engaging in future misconduct in the event he procures employment elsewhere. As for the issue of general deterrence, those members of the regulated community who contemplate using their registrations to divert controlled substances need to know that there will be serious consequences if they choose to do so.

I therefore conclude that the revocation of Respondent's registration is necessary to protect the public interest. And I will further order that any application of Respondent to renew or modify its registration be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration FH0772257 issued to Hills Pharmacy, LLC, be, and it hereby is, revoked. I further order that any application of Hills Pharmacy, LLC, to renew or modify its registration, be, and it hereby is, denied. This order is effective August 29, 2016.

Dated: July 19, 2016.

Chuck Rosenberg,

Acting Administrator.

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Part IV

The President

Proclamation 9471—Anniversary of the Americans with Disabilities Act, 2016
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Presidential Documents

Title 3—

The President

Proclamation 9471 of July 25, 2016

Anniversary of the Americans with Disabilities Act, 2016

By the President of the United States of America

A Proclamation

On July 26, 1990, our Nation marked a pivotal moment in history for Americans with disabilities. Fueled by a chorus of voices who refused to accept a second-class status and driven by a movement that recognized that our country is stronger and more vibrant when we draw on the talents of all our people, the Americans with Disabilities Act (ADA) enshrined into law the notion that Americans living with disabilities deserve to participate in our society free from discrimination. Twenty-six years later, as we mark this anniversary, we recognize all this milestone law has made possible for the disability community.

The ADA sought to guarantee that the places we share—from schools and workplaces to stadiums and parks—truly belong to everyone. It reflects our Nation's full commitment to the rights and independence of people with disabilities, and it has paved the way for a more inclusive and equal society. For the 6.5 million students and the approximately 50 million adults living with mental or physical disabilities, the ADA has swung open doors and empowered each of them to make of their lives what they will.

Building on this progress is a priority for my Administration. The Federal Government has taken the lead in creating meaningful employment opportunities for people with disabilities. In my first term, I issued an Executive Order that called on Federal agencies and contractors to hire more people with disabilities—and today, more Americans with disabilities are working in Federal service than at any time in the last three decades. My Administration has vigorously enforced the Supreme Court's ruling in the Olmstead decision—which determined that, under the ADA, people with disabilities cannot be unnecessarily segregated—and worked to deliver on the promise that individuals with disabilities have access to integrated, community-based services. The Affordable Care Act affirmed that Americans with pre-existing conditions can no longer be denied health insurance, and this year, we made it clear that health care providers must offer reasonable accommodations and ensure effective communication for individuals with disabilities in order to advance health equity and reduce health care disparities.

As we commemorate this progress, we know our work to expand opportunity and confront the stigma that persists surrounding disabilities is not yet finished: We have to address the injustices that linger and remove the barriers that remain. Too many people with disabilities are still unemployed and lack access to skills training or are not paid fairly for their work. We must continue increasing graduation rates for students with disabilities to give them every chance to receive the education and training they need to pursue their dreams. We must make the information and communication technologies we rely on accessible for all people, and ensure their needs are considered and incorporated as we advance the tools of modern life. And we must keep fighting for more consistent and effective enforcement of the ADA in order to prevent discrimination in public services and accommodations.

At a time when so many doubted that people with disabilities could contribute to our economy or support their families, the ADA assumed they could, and guided the way forward. Today, as we reflect on the courage and commitment of all who made this achievement possible, let us renew our obligation to extend the promise of the American dream to all our people, and let us recommit to building a world free of unnecessary barriers and full of deeper understanding of those living with disabilities.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim July 26, 2016, the Anniversary of the Americans with Disabilities Act. I encourage Americans across our Nation to celebrate the 26th anniversary of this civil rights law and the many contributions of individuals with disabilities.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-fifth day of July, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and forty-first.

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Presidential Documents

Proclamation 9472 of July 25, 2016

National Korean War Veterans Armistice Day, 2016

By the President of the United States of America

A Proclamation

In 1950, when Communist armies from the North stormed across the 38th parallel, brave American men and women—though weary of combat in the wake of World War II—stepped forward to defend their brothers and sisters on the Korean Peninsula. Over the course of 3 years, through unforgiving weather and severe danger, nearly 1.8 million Americans joined in the fight and faced down Communism—pushing the invading armies back and protecting a people on the other side of the world. As we mark the 63rd anniversary of the Military Armistice Agreement that brought an end to this war, we pause to honor the strength and resilience of our Korean War veterans, whose spirits and stories serve as an inspiration to continue advancing freedom's cause.

Rising from occupation and ruin, the Republic of Korea today shines as a thriving, modern country, whose people can take comfort in knowing that the commitment of the United States to their stability and security will never waver. Fifty million South Koreans now live in freedom, reaching for their dreams and pursuing opportunities in a vibrant democracy and dynamic economy—always realizing they have a partner who will stand shoulder-to-shoulder with them in defense of peace and prosperity. Our lasting friendship and unbreakable alliance are sustained by the beliefs we hold in common and the values we cherish.

As we pay tribute to the Americans who gallantly helped forge this bond, we know our solemn responsibilities to our fallen and their loved ones persist long after the battle ends. More than 7,800 Americans are still missing from the Korean War, and we will not stop working to live up to our obligations to their families. We owe all our service members an enormous debt of gratitude. To honor the full weight of the sacrifices made by those who serve, we must uphold our Nation's promise to our veterans when they return home, and fulfill our commitment to all who wear the uniform in our name.

On National Korean War Veterans Armistice Day, we pay tribute to the American patriots who fought for freedom and democracy throughout the Korean War, leaving behind everyone they loved to secure the blessings of liberty for a country they never knew and a people they had never met. For the heavy price they paid, we will forever honor the legacy of their service and uphold the ideals they secured through this hard-won victory.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim July 27, 2016, as National Korean War Veterans Armistice Day. I call upon all Americans to observe this day with appropriate ceremonies and activities that honor our distinguished Korean War veterans.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-fifth day of July, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and forty-first.

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